U.S. Department of Health and Human Services

HRSA

Health Resources and Services Administration

SF-424 R&R
Two-Tier Application Guide

A guide developed and maintained by HRSA for preparing and submitting <u>two-tier</u> applications through Grants.gov <u>AND</u> the HRSA Electronic Handbooks (EHBs) using the SF-424 R&R Application Package

(This "version 2" R&R two-tier guide applies to HRSA's FY17 R&R two-tier FOAs posted *after* June 1, 2016)

Updated June 1, 2016

Table of Contents

1. INTRODUCTION

1.1. About HRSA

HRSA's mission is to improve health and achieve health equity through access to quality services, a skilled health workforce and innovative programs. HRSA provides access to essential health care services for people who are low-income, uninsured, or live in rural areas or urban neighborhoods where access to or availability of health care is limited. HRSA provides leadership and financial support to health care providers in every state and U.S. territory. HRSA-funded health centers provide medical care to more than 20 million patients each year at more than 8,500 sites nationwide. HRSA awardees provide health care to uninsured people, people living with HIV/AIDS, and pregnant women, mothers and children. They train health professionals and improve systems of care in rural communities.

HRSA oversees organ, bone marrow and cord blood donation. It supports programs that compensate individuals harmed by vaccination and maintains databases that protect against health care malpractice and health care waste, fraud and abuse. For more information please visit our website at http://www.hrsa.gov.

1.2. Document Purpose and Scope

The purpose of this document is to provide detailed instructions to help you (the applicant organization/agency) prepare and submit two-tier new, competing continuation, and competing supplement applications electronically to HRSA through Grants.gov **and** the HRSA Electronic Handbooks (EHBs), as specified in the funding opportunity announcement (FOA). This *SF-424 R&R Two-Tier Application Guide* is specific to FOA using the Application for Federal Assistance SF-424 Research and Related (R&R) application package**** for research or training awards, for applicants that are required to submit initial information electronically through Grants.gov, and subsequent information through the EHBs**. This *Guide* is intended to be a concise source of HRSA general information related to the application preparation and submission process and will be updated periodically. This document does not replace program-specific guidance provided in FOAs. This document also does not replace the Health and Human Services Grants Policy Statement (HHS GPS), which serves as the comprehensive source of grant information across the Department.

Note: As of October 1, 2010 current awardees are no longer required to submit a full application to determine eligibility for funding of a successive budget period within their approved project period. Instead, awardees need only to submit the streamlined Non-Competing Continuation (NCC) Progress Report for continued funding of the next budget period. For details and user guides, please visit http://www.hrsa.gov/grants/noncompetingcontinuations/index.html.

If you are applying for awards that require the SF-424 Non-Construction application package, you must refer to HRSA's *SF-424 Application Guide* (where **no supplemental EHB information is required) at http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf for guidance. If you are applying for awards that require the SF-424 R&R application package (where **no** supplemental EHBs information is required), you must refer to HRSA's *SF-424 R&R Application Guide* at http://www.hrsa.gov/grants/apply/applicationguide/sf424rrguidev2.pdf.

1.3. Document Version Control

This document is periodically updated and maintained by HRSA's Office of Federal Assistance Management, Division of Grants Policy.

1.4. Summary of Significant Changes

6/1/16:

- Mandatory Disclosures details/contact information added in Section 2.2. Administrative and National Policy Requirements.
- National HIV/AIDS Strategy (NHAS) section updated (includes pre-exposure prophylaxis (PrEP) and HIV Care Continuum information) in Section 2.2. Administrative and National Policy Requirements.
- Funding Restrictions section updated with a listing of legislative mandates in Section 5.1.iv. Budget.
- Biographical sketch guidance moved out of R&R Guide/Appendix and into individual program FOAs.
- Supplemental Instructions for Preparing the Protection of Human Subjects Section revised.

2/12/16:

- All references/information related to P.L. 113-235 updated to P.L. 114-113, the Consolidated Appropriations Act, 2016.
- "Cultural and Linguistic Competence" language updated in Section 2.2. Administrative and National Policy Requirements.
- Salary Limitation information/amounts updated in Sections 5.1.*iv. Budget* and *v. Budget Justification Narrative (Personnel Costs).*
- Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification added to Section 5.1.*viii. Certifications*.

8/10/15: The "Non-Discrimination Requirements" section has been enhanced and renamed "Accessibility Provisions and Non-Discrimination Requirements."

5/14/15: Various updates/requirements per the Uniform Guidance including: Mandatory Disclosure, Classification of Costs.

2. POLICIES, ASSURANCES, DEFINITIONS AND OTHER INFORMATION

2.1. HHS Grants Policy Statement

HRSA grant and cooperative agreement awards are subject to the requirements of the HHS GPS that are applicable based on recipient type and purpose of award. This includes any requirements in Parts I and II of the HHS GPS that apply to the award. The HHS GPS is available at http://www.hrsa.gov/grants/hhsgrantspolicy.pdf. The general terms and conditions in the HHS GPS will apply as indicated unless there are statutory, regulatory, or award-specific requirements to the contrary (as specified in the Notice of Award (NoA)).

2.2. Administrative and National Policy Requirements

Effective December 26, 2014, all administrative and audit requirements and the cost principles that govern federal monies associated with an application and award are subject to the Uniform Guidance 2 CFR part 200 as codified by HHS at 45 CFR part 75, which supersede the previous administrative and audit requirements and cost principles.

Successful applicants must comply with the administrative requirements outlined in 45 CFR part 75 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards.

In addition to the numerous administrative and national policy requirements imposed by regulation and by the HHS GPS, HRSA stresses the following terms of every award:

Accessibility Provisions and Non-Discrimination Requirements
Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please seehttp://www.hhs.gov/civil-rights/for-

individuals/special-topics/limited-english-proficiency/index.html. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html; andhttp://www.hhs.gov/civil-rights/for-providers/index.html . Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html. Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.

Acknowledgement of Federal Funding

HRSA requires recipients to use the following acknowledgement and disclaimer on all products produced by HRSA funds:

> "This project is/was supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number and title for grant amount (specify grant number, title, total award amount and percentage financed with nongovernmental sources). This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS or the U.S. Government."

Recipients are required to use this language when issuing statements, press releases, requests for proposals, bid solicitations, and other HRSA supported publications and forums describing projects or programs funded in whole or in part with HRSA funding. Examples of HRSA-supported publications include, but are not limited to, manuals, toolkits, resource guides, case studies and issues briefs.

Affordable Care Act Outreach and Education

It is important to note that a healthier country is one in which more Americans are able to access the care they need to prevent the onset of disease and manage disease when it is present. Insurance coverage is strongly related to better health outcomes for both children and adults. Access to insurance improves health outcomes by helping people obtain preventive and screening services, prescription drug benefits, mental health and other services, and by improving continuity of care.

The Affordable Care Act, the health care law of 2010, creates new state-based marketplaces, also known as exchanges, to offer millions of Americans new access to affordable health insurance coverage. Individuals with incomes between 100 to 400 percent FPL may be eligible to receive advance payments of premium tax credits and/or

cost-sharing reductions to help pay for the cost of enrolling in a qualified health insurance plan and paying for coverage of essential health benefits. In states that choose to participate in the Affordable Care Act expansion of Medicaid to non-disabled adults with incomes of up to 133 percent of Federal Poverty Level (FPL), this provision will provide new coverage options for many individuals who were previously ineligible for Medicaid. In addition, the law helps make prevention affordable and accessible for Americans by requiring health plans to cover certain recommended preventive services without cost sharing.

Outreach efforts would ensure that families and communities understand these new developments and would provide eligible individuals the assistance they need to secure and retain coverage as smoothly as possible during the transition and beyond. You are encouraged to share information with your beneficiaries about these options and to assist them, to the extent it is an appropriate activity under your award, in enrolling in available insurance plans or in finding other available sources of payment for the services you provide.

To learn more about the Health Insurance Marketplace and enroll in coverage, visit HealthCare.gov. Awardees should direct individuals, families, and partners to HealthCare.gov to access educational information and create accounts, complete an online application, shop for qualified health plans, and enroll in coverage. The site is also available in Spanish at CuidadoSalud.gov (https://www.cuidadodesalud.gov/es/).

A wide range of enrollment and education assistance is available. Individuals can go to https://localhelp.healthcare.gov to find a trained in-person assistor in their community, use the live chat function on HealthCare.gov, or contact the Health Insurance Marketplace call center toll free at 1-800-318-2596 (TTY 1-855-889-4325), which is available 24/7 in 150 languages.

For more information on the marketplaces and the health care law, visit http://www.healthcare.gov/. In addition, for professionals learning about the Marketplace and helping people apply, get the latest resources at http://marketplace.cms.gov/.

Cultural and Linguistic Competence

HRSA programs serve culturally and linguistically diverse communities that are not just defined by race or ethnicity, but also socio-economic status, sexual orientation, gender identity, physical and mental ability, age, and other factors. Organizational behaviors, practices, attitudes, and policies across all HRSA-supported entities respect and respond to the cultural diversity of communities, clients and students served.

HRSA is committed to ensuring access to quality health care for all. Quality care means access to services, information, and materials delivered by competent providers in a manner that factors in the language needs, health literacy, culture, and diversity of the populations served. Quality also means that data collection instruments used should

adhere to culturally competent and linguistically appropriate norms. For additional information and guidance, refer to the National Standards for Culturally and Linguistically Appropriate Services (CLAS) published by the U.S. Department of Health and Human Services at https://www.thinkculturalhealth.hhs.gov/. Additional cultural/linguistic competency and health literacy tools, resources and definitions are available online at http://www.hrsa.gov/culturalcompetence and http://www.hrsa.gov/healthliteracy.

DOMA: Implementation of United States v. Windsor and Federal Recognition of Same-Sex Spouses/Marriages

References: United States v. Windsor, 133 S.Ct. 2675 (June 26, 2013); § 3 of the Defense of Marriage Act, codified at 1 USC § 7.

The following applies to **all HRSA grant programs except:**

- block grants governed by 45 CFR part 96,
- block grants governed by 45 CFR part 98, and
- grant awards made under titles IV-A, XIX and XXI of the Social Security Act.

A standard term and condition of award will be included in the NoA that states: "In any grant-related activity in which family, marital, or household considerations are, by statute or regulation, relevant for purposes of determining beneficiary eligibility or participation, grantees must treat same-sex spouses, marriages, and households on the same terms as opposite-sex spouses, marriages, and households, respectively. By "same-sex spouses," HHS means individuals of the same sex who have entered into marriages that are valid in the jurisdiction where performed, including any of the 50 states, the District of Columbia, or a U.S. territory or in a foreign country, regardless of whether or not the couple resides in a jurisdiction that recognizes same-sex marriage. By "same-sex marriages," HHS means marriages between two individuals validly entered into in the jurisdiction where performed, including any of the 50 states, the District of Columbia, or a U.S. territory or in a foreign country, regardless of whether or not the couple resides in a jurisdiction that recognizes same-sex marriage. By "marriage," HHS does not mean registered domestic partnerships, civil unions or similar formal relationships recognized under the law of the jurisdiction of celebration as something other than a marriage."

Financial Conflict of Interest

HHS requires awardees and investigators to comply with the requirements of 42 CFR part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." A Final Rule amending this PHS regulation (and the companion regulation at 45 CFR part 94, "Responsible Prospective Contractors," imposing similar requirements for research contracts) was published on August 25, 2011 in the Federal Register (http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf). An Institution applying for or receiving PHS funding from a grant or cooperative agreement that is covered by the rule must be in full compliance with all of

the revised regulatory requirements no later than August 24, 2012, and immediately upon making its institutional Financial Conflict of Interest (FCOI) policy publicly accessible as described in the regulation.

Health IT
Health information technology (Health IT) provides the basis for improving the overall quality, safety and efficiency of the health delivery system. HRSA endorses the widespread and consistent use of health IT, which is the most promising tool for making health care services more accessible, efficient and cost effective for all Americans.

Related Health IT Resources:

- Health Information Technology (HHS): http://www.healthit.gov/
- What is Health Care Quality and Who Decides? (AHRQ): http://www.ahrq.gov

Healthy People 2020
Healthy People 2020 is a national initiative led by HHS that sets priorities for all HRSA programs. The initiative has four overarching goals: (1) attain high-quality, longer lives free of preventable disease, disability, injury, and premature death; (2) achieve health equity, eliminate disparities, and improve the health of all groups; (3) create social and physical environments that promote good health for all; and (4) promote quality of life, healthy development, and healthy behaviors across all life stages. The program consists of over 40 topic areas, containing measurable objectives. HRSA has actively participated in the work groups of all the topic areas and is committed to the achievement of the Healthy People 2020 goals. More information about Healthy People 2020 may be found online at http://www.healthypeople.gov/.

Human Subjects Protection
Federal regulations (45 CFR 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If research involving human subjects is anticipated, awardees must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in the Code of Federal Regulations, Title 45 – Public Welfare, Part 46 – Protection of Human Subjects (45 CFR 46), available online at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

NOTE: Please see the Appendix of this *SF-424 R&R Two-Tier Application Guide* for supplemental instructions for preparing the human subjects section of the research plan.

Integrating Primary Care and Public Health

Integration of primary care and public health links people, policy, programs and activities to increase efficiency and effectiveness and ultimately improve population health. Both primary care and public health emphasize prevention as a key driver of better health, and integration of the two fields can transform our focus on disease and treatment to health and wellness, as well as maximize our health care system investment. Integration occurs on a continuum and includes mutual awareness, cooperation, collaboration and partnership. Successful integration requires primary care and public health to work together along this continuum and address social and environmental determinants of health, engage communities, align leadership, develop the healthcare workforce, sustain systems, and share and collaborate on the use of data and analysis – all with an eye toward achieving a shared goal of population health improvement. Integration of primary care and public health is a major focus for HRSA and HHS, and to the extent possible, you should consider ways to integrate primary care and public health in the activities they pursue. More information can be found at http://www.hrsa.gov/publichealth/.

Mandatory Disclosures

The non-federal entity or applicant for a federal award must disclose, in a timely manner, in writing to the HHS awarding agency or pass-through entity all violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award (45 CFR § 75.113). Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. 3321).

Submission is required for all applicants and recipients, in writing, to the awarding agency and to the HHS Office of Inspector General (OIG) all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Disclosures must be sent in writing to:

HRSA (The Awarding Agency)

AND

U.S. Department of Health and Human Services
Office of Inspector General
ATTN: Mandatory Grant Disclosures, Intake Coordinator
330 Independence Avenue, SW, Cohen Building
Room 5527
Washington, DC 20201
URL: http://oig.hhs.gov/fraud/report-fraud/index.asp
(Include “Mandatory Grant Disclosures” in subject line)
Fax: (202) 205-0604 (Include “Mandatory Grant Disclosures” in subject line) or
E-mail: MandatoryGranteeDisclosures@oig.hhs.gov

National HIV/AIDS Strategy (NHAS): Updated to 2020

The National HIV/AIDS Strategy for the United States: Updated to 2020 (NHAS 2020 or Strategy) is a five-year plan that details principles, priorities, and actions to guide the national response to the HIV epidemic. To the extent possible, program activities should strive to support the primary goals of NHAS 2020:

1) Reduce new HIV infections;
2) Increase access to care and optimize health outcomes for people living with HIV (PLWH);
3) Reduce HIV-related health disparities and health inequities; and
4) Achieve a more coordinated national response to the HIV epidemic.

Updated in 2015, NHAS 2020 has fully integrated the objectives and recommendations of the HIV Care Continuum Initiative (see below) and the Federal Interagency Working Group on the Intersection of HIV/AIDS, Violence against Women and Girls, and Gender-Related Health Disparities. The Strategy also allows opportunities to refocus and strengthen the ongoing work in HIV prevention, care, and research.

Recipients should take action to align their organization's efforts, over the next five years, around the Strategy's four areas of critical focus:

- Widespread testing and linkage to care, enabling PLWH to access treatment early;
- Broad support for PLWH to remain engaged in comprehensive care, including support for treatment adherence;
- Universal viral suppression among PLWH; and
- Full access to comprehensive pre-exposure prophylaxis (PrEP) services for those to whom it is appropriate and desired, and support for medication adherence for those using PrEP.

More information on how recipients can support NHAS 2020, including the Community Action Plan Framework, a tool to help recipients and other stakeholders in developing their own plans to implement NHAS 2020, can be found here: https://aids.gov/federal-resources/national-hiv-aids-strategy/overview/.

HIV Care Continuum

The HIV care continuum includes the diagnosis of HIV, linkage to HIV medical care, lifelong retention in HIV medical care, appropriate prescription of ART, and, ultimately, HIV viral load suppression. The HIV care continuum performance measures align with the [U.S. Department of Health and Human Services] HHS Common HIV Core Indicators, approved by the HHS Secretary. RWHAP recipients and providers submit data through the RSR. HAB collects the data elements needed to produce the HHS Common HIV Core Indicators (Indicators); uses the data to calculate Indicators, across

the entire RWHAP; and reports six of the seven Indicators to the HHS, Office of the Assistant Secretary for Health.

RWHAP recipients are encouraged to assess the outcomes of their programs along the HIV care continuum and work with their community and public health partners to improve outcomes, so that individuals diagnosed with HIV are linked to and engaged in care and started on ART as early as possible. HAB requests that recipients use the RWHAP performance measures, at their local level, to assess the efficacy of their programs and to analyze and improve the gaps along the HIV care continuum.

Pilot Program for Enhancement of Contractor Employee Whistleblower Protections

Awards issued under HRSA FOAs are subject to the requirements of 48 CFR § 3.908. A standard term and condition of award requires that awardees inform their employees in writing of employee whistleblower rights and protections under 41 U.S.C. 4712 in the predominant native language of the workforce. (Regarding 48 CFR § 3.908, note that use of the term "contract," "contractor," "subcontract," or "subcontractor" for the purpose of this term and condition, should read as "grant," "grantee," "subgrant," or "subgrantee.")

Research Misconduct

The recipient is responsible for the actions of its employees and other research collaborators, including third parties, involved in the project. The recipient will inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged or apparent research misconduct. 42 CFR part 93, "Public Health Service Policies on Research Misconduct," specifies recipient responsibilities for dealing with and reporting possible research misconduct. The regulation is available from the Office of Research Integrity (ORI) on its home page (http://www.ori.dhhs.gov).

The recipient must carry out its responsibilities with extra care if a research misconduct inquiry has been initiated as specified in 42 CFR § 93.307 or if the recipient or ORI has made a finding of research misconduct. The recipient must report promptly to ORI any incident of alleged or apparent research misconduct that it judges as warranting investigation and must advise ORI of any decision to initiate an investigation. The recipient also must notify ORI if it intends to close a case at the inquiry or investigation stage based on an admission of responsibility, settlement, or for any other reason. The regulations also require that the recipient submit an annual report.

If a misconduct investigation has been initiated, the recipient must take any necessary steps, in addition to its normal and ongoing responsibilities under the grant, to protect the scientific integrity of the project, protect human subjects and animals, provide reports to ORI, and ensure the proper expenditure of funds and continuation of the project during the investigation, if appropriate. ORI staff members are available to help recipients with investigating and reporting on research misconduct, and POs are

available to provide technical assistance and to work with recipients to protect funded projects from the adverse effects of research misconduct.

If the recipient finds research misconduct by anyone working on an HHS grant-supported project, whether at its organization or at a third-party organization, the recipient must assess the effect of that finding on the ability to continue that project, as originally approved, and must promptly request OPDIV prior approval of any intended change of PI or other key personnel (see "Prior Approval Requirements—OPDIV Prior Approval" in the HHS GPS). In addition, the awarding office may impose sanctions, such as withdrawal of approval of the PI/PD or other key personnel, disallowance of costs associated with the invalid or unreliable research, withholding a non-competing continuation award, suspension or termination, in whole or in part, of the current award, or debarment.

If research misconduct has affected data validity or reliability, ORI or the OPDIV may require the recipient and its employee/collaborator authors to submit a correction or retraction of the data to a journal, publish the corrected data, or both. If the recipient does not comply with this requirement, the OPDIV may invoke its rights, under 45 CFR part 74 or 92, to access the data (including copyrightable material developed under the award), have the data reviewed, and submit the correction.

The recipient must promptly report issues involving potential civil or criminal fraud, such as false claims or misappropriation of federal funds, to the HHS OIG.

Smoke-Free Workplace

The Public Health Service strongly encourages all award recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. Further, Public Law (P.L.) 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

Standards for Financial Management

Recipients are required to meet the standards and requirements for financial management systems set forth in 45 CFR part 75, as applicable. The financial systems must enable the recipient to maintain records that adequately identify the sources of funds for federally assisted activities and the purposes for which the award was used, including authorizations, obligations, unobligated balances, assets, liabilities, outlays or expenditures, and any program income. The system must also enable the recipient to compare actual expenditures or outlays with the approved budget for the award.

HRSA funds must retain their award-specific identity—they may not be commingled with state funds or other federal funds. ["Commingling funds" typically means depositing or recording funds in a general account without the ability to identify each specific source of funds for any expenditure.]

Trafficking in Persons
Awards issued under HRSA FOAs are subject to the requirements of Section 106(g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. 7104). For the full text of the award term, go to http://www.hrsa.gov/grants/trafficking.html.

NOTE: The signature of the AOR (by checking "I agree" in Box 17 of SF-424 R&R) on the application serves as the required certification of compliance for your organization regarding the administrative and national policy requirements.

2.3. Compliance Requirements at a Glance

For reference, the chart below provides compliance requirements by recipient and requirement type.

Compliance Requirements at a Glance			
Recipient Type	**Administrative Requirements**	**Cost Principles**	**Audit Requirements**
State, Local, & Tribal Governments	45 CFR part 75	45 CFR 75; Subpart E	45 CFR 75; Subpart F
Colleges & Universities			
Non-Profits			
Hospitals		45 CFR part 75, Appendix IX	
For-Profits		48 CFR Subpart 31.2 (FAR 31.2)	
Foreign		As stated above for each awardee type	45 CFR part 75 except where the HHS awarding agency determines that the application of these subparts would be inconsistent with the international obligations of the United States or the statutes or regulations of a foreign government.

2.4. Assurances and Certifications

Complete Application Form SF-424B Assurances – Non-Construction Programs.

The signature of the AOR (by checking "I agree" in Box 17 of SF-424 R&R) on the application serves as the required certification of compliance for the applicant organization regarding Lobbying. See Section 5.1.viii of this *SF-424 R&R Two-Tier Application Guide* for more details. If applicable, complete the Standard Form-LLL Disclosure of Lobbying Activities Form provided with the application package.

2.5. References

About HRSA
http://www.hrsa.gov/about/index.html

Grants.gov Online User Guide
http://www.grants.gov/help/html/help/index.htm

How to Apply for a Grant
http://www.hrsa.gov/grants/apply/index.html

Tips for Preparing Grant Proposals
http://www.hhs.gov/grants/grants/get-ready-for-grants-management/tips-for-preparing-grant-proposals

System for Award Management (SAM) – https://www.sam.gov

2.6. Definitions

Term	Definition
508 Compliant	Section 508 of the Rehabilitation Act (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 (P.L. 105-220), August 7, 1998 requires that all Web site content be equally accessible to people with disabilities. This applies to Web applications, Web pages and all attached files. It applies to intranet as well as public-facing Web pages. For more information, visit http://www.hrsa.gov/about/508Resources.html.
Administrative Requirements	The general practices that are common to the administration of federal awards, such as financial accountability, reporting, equipment management, and retention of records.

Allocable Cost	A cost that is allocable to a particular cost objective (i.e., a specific function, grant/cooperative agreement project, service, department, or other activity) in accordance with the relative benefits received. A cost is allocable to a federal award where it is treated consistently with other costs incurred for the same purpose in like circumstances and (1) is incurred specifically for the award, (2) benefits both the award and other work and can be distributed in reasonable proportion to the benefits received, and (3) is necessary for the overall operation of the organization.
Allowable Cost	A cost incurred by a recipient that is reasonable for the performance of the award; allocable; in conformance with any limitations or exclusions set forth in the federal cost principles applicable to the organization incurring the cost or in the NoA as to the type or amount of cost; consistent with regulations, policies, and procedures of the recipient that are applied uniformly to both federally supported and other activities of the organization; accorded consistent treatment as a direct or indirect cost; determined in accordance with generally accepted accounting principles; and not included as a cost in any other federally supported award (unless specifically authorized by statute).
Assurance	A written statement by an applicant, normally included with the application, indicating that it will abide by a particular requirement if an award is made.
Authorized Organization Representative (AOR)	An AOR is a role in Grants.gov. AORs are the individuals named by the applicant/recipient organization, who are authorized to act for the applicant/recipient and to assume the obligations imposed by the federal laws, regulations, requirements, and conditions that apply to applications or awards. AORs are approved by the organization's E-Business Point of Contact and are authorized and designated to submit applications through Grants.gov on behalf of an organization.
Authorizing Official (AO)	An Authorizing Official is a role in the HRSA Electronic Handbooks (EHBs). In the event that an application or portion of an application is to be submitted through the EHBs (IF indicated in the FOA), this individual is responsible for certifying and submitting it to HRSA.
Award	The document that provides HRSA funds to a recipient to carry out an approved program or project (based on an approved application or progress report). The term, when used as a noun, is sometimes used interchangeably with "grant" or "cooperative agreement."

Budget Periods	The intervals of time (usually 12 months each) into which a project period is divided for budgetary and funding purposes. Funding of individual budget periods sometimes is referred to as “incremental funding.”
Chief Grants Management Officer (CGMO)	The CGMO is HRSA’s representative on federal award policy directives and award administration matters.
Competing Continuation Application	A request for funding to renew, by one or more additional budget periods (described as a “competitive segment”), a project period that would otherwise expire. This type of application is sometimes referred to as “renewal.” These applications must compete for support in the same manner as new applications. (“Type 2 award”)
Competing Supplement Application	A request in response to an FOA for an increase in support in a current budget period for expansion of the scope of the approved project or program. (“Type 3 award”)
Consumer/Provider Board Participation	Allowable costs in accordance with applicable program regulations. When not specifically authorized by program regulations, only the following costs are allowable with OPDIV prior approval: • Reasonable and actual out-of-pocket costs incurred solely as a result of attending a scheduled meeting, including transportation, meals, babysitting fees, and lost wages. • The reasonable costs of necessary meals furnished by the recipient to consumer or provider participants during scheduled meetings if not reimbursed to participants as per diem or otherwise. Where programmatic regulations permit such payments but establish a maximum annual income for eligibility for reimbursement of consumer/provider board members for wages lost by reason of their participation in board activities, the determination of eligibility will be made on the basis of gross rather than net income. Members of consumer/provider boards are not considered employees or consultants of the recipient. Therefore, they may not be compensated for their services other than as above, nor are they eligible for associated fringe benefits. Although not eligible for individual insurance coverage, board members may be covered by an organizational insurance policy while acting in their official capacities as board members.

Cooperative Agreement	A legal instrument of financial assistance used when there will be substantial federal programmatic involvement. Substantial involvement means that HRSA program staff will collaborate or participate in project or program activities as specified in the FOA and NoA. See full definition at 45 CFR § 75.2 Definitions.
Cost Principles	The government-wide principles, issued by OMB (or, in the case of commercial organizations, the Federal Acquisition Regulation, or in the case of hospitals, 45 CFR part 75, Appendix IX, "Principles For Determining Costs Applicable to Research and Development Under Grants and Contracts With Hospitals"), on allowability and unallowability of costs under federally sponsored agreements.
Cost Sharing or Matching	The portion of project costs not paid by the federal funds (unless otherwise authorized by federal statute). This may include the value of allowable third party in-kind contributions, as well as expenditures by the recipient. Costs used to satisfy matching or cost-sharing requirements are subject to the same policies governing allowability as other costs under the approved budget.
DUNS Number	Data Universal Numbering System (DUNS) number, is a nine-digit number established and assigned by Dun and Bradstreet to currently uniquely identify a business entity. This number is also known as the Unique Entity Identifier.
Equipment	An article of tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level established by the non-federal entity for financial statement purposes, or $5,000.
Executive Order 12372 (Intergovernmental Review of Federal Programs)	The source of the requirement that state and local officials review certain proposed federal financial assistance. For those states that participate in the process, a single state official or organization is designated for coordination of the review process and to send official state process comments and recommendations to federal agencies. These state officials or organizations are referred to as State Single Points of Contact. (45 CFR part 100, "Intergovernmental Review of Department of Health and Human Services Programs and Activities is the HHS implementation of the Executive order.)
Federal Award Identification Number (FAIN)	The FAIN is a unique number assigned to each federal award by the awarding agency (aka "grant number" it's the 10-digit number found in box 4b of the NoA). This number is used on all award documents. Pass-through entitites are required to inform subrecipients of this number and associated requirements of use.

Funding Opportunity Announcement (FOA)	HRSA's formally issued announcement of the availability of federal funding through one of its financial assistance programs. The announcement invites applications and provides such information as eligibility and evaluation criteria, funding preferences/priorities, how to obtain application packages, and the submission deadline.
Funding Preference	The funding of a specific category or group of applications ahead of other categories or groups of applications that are recommended for approval. If the authorizing legislation provides a funding preference for some applicants, applicants that meet the criteria for the preference will be placed in a more competitive position among applications that can be funded. Applications that do not receive a funding preference will be given full and equitable consideration during the review process.
Funding Priority	The favorable adjustment of combined review scores of individually approved applications when applications meet specified criteria. An adjustment is made by a set, pre-determined number of points.
Funding Special Consideration	A special consideration is defined as the favorable consideration of an application by HRSA funding officials, based on the extent to which the application addresses the specific area of special consideration.
Grant	A legal instrument of financial assistance between a federal awarding agency or pass-through entity and a non-federal entity that, consistent with 31 U.S.C. 6302, 6304, is used to enter into a relationship the principal purpose of which is to transfer anything of value from the federal awarding agency or pass-through entity to the non-federal entity to carry out a public purpose authorized by a law of the United States (see 31 U.S.C. 6101(3)); and not to acquire property or services for the federal awarding agency or pass-through entity's direct benefit or use. A grant is used whenever HRSA anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities. See full definition at 45 CFR § 75.2 Definitions.

Grants Management Officer (GMO)	The GMO is the official whose name appears on the NoA and is the individual designated to serve as the HHS official responsible for the business and non-programmatic management aspects of a particular grant(s) or cooperative agreement(s). In this capacity, the GMO is responsible for all federal business management matters associated with the review, negotiation, award, and administration of the assigned grants/cooperative agreements and interprets federal award administration policies and provisions. The Grants Management Officer also serves as the counterpart to the business officer of the recipient organization. The GMO is the only official authorized to obligate HRSA to the expenditure of federal funds or to change the funding, duration, or other terms and conditions of an award.
Grants Management Specialist (GMS)	The GMS works with the GMO on the day-to-day business and nonprogrammatic management of a portfolio of HRSA grants and cooperative agreements. The GMS performs many of the activities described above on behalf of the GMO and is usually the primary point of contact for recipients when dealing with award-related issues. He/she also works closely with the federal project officer (PO) or program official aka program contact (PC).
Indirect Cost Rate	The rate negotiated by the cognizant federal agency that is used as the basis for reimbursing indirect costs. The rate may be applicable to an entire organization, on-site activities or off-site activities only, a particular site, or specified activities. The rate must be effective for the period for which reimbursement is claimed. Rates may be fixed, predetermined, provisional, or final, consistent with the applicable federal cost principles.
Indirect Cost Rate Agreement	The document that formalizes the establishment of an indirect cost rate(s) and provides information on the proper application of the rate(s).
Indirect Costs	Costs incurred for common or joint objectives which cannot be readily and specifically identified with a particular project or program but are necessary to the operations of the organization, e.g., the cost of operating and maintaining facilities, depreciation, and administrative salaries. For some institutions, the term “facilities and administration” (F&A) is used to denote indirect costs. Reminder: Indirect costs should be calculated within the total requested costs.
Institutional Review Board (IRB)	An Institutional Review Board is a committee that performs ethical review of proposed research.

Key Personnel	Per the HHS GPS, the PI/PD and other individuals who contribute to the programmatic development or execution of a project or program in a substantive, measurable way, whether or not they receive salaries or compensation under the grant.
Letter of Intent	A preliminary, non-binding indication of an organization's intent to submit an application.
Local Government	Any unit of government within a state, including a county, borough, municipality, city, town, township, parish, local public authority (including any public housing agency under the United States Housing Act of 1937), school district, special district, intrastate district, council of governments (whether or not incorporated as a nonprofit corporation under state law), and any other agency or instrumentality of a multi-, regional, or intra-state or local government. The term does not include institutions of higher education and hospitals.
Matching	See Cost Sharing.
Maintenance of Effort	A requirement contained in the authorizing statute or program regulations stating that, in order to receive federal grant funds, a recipient must agree to maintain a specified level of financial effort (using a specified baseline period, such as the year prior to the initiation of federal award support) for the grant from its own resources and other non-federal sources.
Modified Total Direct Cost (MTDC)	*Modified Total Direct Cost (MTDC) means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and up to the first $25,000 of each subaward (regardless of the period of performance of the subawards under the award). MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of $25,000. Other items may only be excluded when necessary to avoid a serious inequity in the distribution of indirect costs, and with the approval of the cognizant agency for indirect costs. *This definition applies to rate agreements negotiated on/after 12/27/2014 and to entities without an indirect cost rate agreement using the 10% de minimis rate.
New Application	A request for financial assistance for a project or activity that is not currently receiving support. A new application is required for consideration under a competitive FOA.,

Non-Competing Continuation	Funding for the second or subsequent budget period within an approved competitive segment that is released following submission and HRSA approval of a progress report. A non-competing continuation application does not compete with other applications for support. For details and user guides, please visit http://www.hrsa.gov/grants/noncompetingcontinuations/index.html.
Non-Federal Entity	Non-federal entity means a state, local government, Indian tribe, institution of higher education (IHE), or non-profit organization that carries out a federal award as a recipient or subrecipient.
Non-profit Organization	Any corporation, trust, association, cooperative, or other organization, not including IHEs, that: is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized primarily for profit; and uses net proceeds to maintain, improve, or expand the operations of the organization.
Notice of Award (NoA)	The NoA is the official document, signed (or the electronic equivalent of signature) by a GMO that: (1) notifies the recipient of the award of a grant or cooperative agreement; (2) contains or references all the terms and conditions of the grant and federal funding limits and obligations; and, (3) provides the documentary basis for recording the obligation of federal funds in the HRSA accounting system.
Objective Review	An advisory review of discretionary award applications conducted by unbiased reviewers with expertise in the programmatic area for which applications are submitted.
Pre-Award Costs	Costs incurred prior to the beginning date of the project period, in anticipation of an award and at the applicant's own risk, for otherwise allowable costs.

Principal	Per 2 CFR § 180.995, (a) An officer, director, owner, partner, principal investigator, or other person within a participant with management or supervisory responsibilities related to a covered transaction; or (b) A consultant or other person, whether or not employed by the participant or paid with federal funds, who— (1) Is in a position to handle federal funds; (2) Is in a position to influence or control the use of those funds; or, (3) Occupies a technical or professional position capable of substantially influencing the development or outcome of an activity required to perform the covered transaction. Per 2 CFR § 376.995, Individuals, in addition to those listed at 2 CFR § 180.995, who participate in HHS covered transactions including: (a) Providers of federally required audit services; and (b) Researchers.
Program Contact (PC)	HRSA staff person listed in the FOA to answer programmatic questions.
Progress Report	Periodic, usually annual, reports submitted by the recipient and used by HRSA to assess progress and, except for the final progress report, to determine whether to provide funding for the budget period subsequent to that covered by the report.
Project Officer / Program Official (PO)	The PO is the HRSA official responsible for the programmatic, scientific, and/or technical aspects of assigned applications and grants/cooperative agreements. The PO's responsibilities include, but are not limited to, development of programs to meet HRSA's mission; preparation of FOAs; provision of programmatic technical assistance; post-award monitoring of project/program performance, including review of progress reports and making site visits; and other activities complementary to those of the GMS. The PO and the GMS work as a team in many of these activities. For the purposes of this document, the PO may also be referred to as the program contact (PC).
Project or Program Costs	The total allowable costs incurred under a federal award and all required cost sharing and voluntary committed cost sharing, including third-party contributions.
Project Period	The total time for which support of a project has been programmatically approved. The total project period comprises the initial competitive segment, any subsequent competitive segments resulting from a competing continuation award, and any non-competing extensions. Project periods are comprised of 12-month budget periods.

Reasonable Cost	A cost whose nature or amount does not exceed that which would be incurred by a prudent person under the circumstances prevailing when the decision was made to incur the cost.
Recipient	The organization or individual that receives a grant or cooperative agreement award directly from HRSA and is responsible and accountable for the use of the funds provided and for the performance of the HRSA-supported project or activity. The recipient is the entire legal entity even if a particular component is designated in the NoA. The term includes "grantee" and "awardee." The term recipient does not include subrecipients.
Research	A systematic study directed toward fuller scientific knowledge or understanding of the subject studied. "Development" is the systematic use of knowledge and understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes. NOTE: Applicants applying for research grants and using the SF-424 R&R should refer to the Application Guide for SF-424 R&R (Research) for guidance.
Research Misconduct	Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. The term does not include honest error or differences of opinion.

State	Unless otherwise defined in programmatic statute, any state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and any agency or instrumentality thereof exclusive of local governments. State institutions of higher education and state hospitals are not considered state governments for purposes of the HHS general administrative requirements for grants and the HHS GPS.
Subaward	An award provided by a pass-through entity to a subrecipient for the subrecipient to carry out part of a federal award received by the pass-through entity. It does not include payments to a contractor or payments to an individual that is a beneficiary of a federal program. A subaward may be provided through any form of legal agreement, including an agreement that the pass-through entity considers a contract. The term includes consortium agreements.
Subrecipient	A non-federal entity that receives a subaward from a pass-through entity to carry out part of a federal program; but does not include an individual that is a beneficiary of such program. A subrecipient may also be a recipient of other federal awards directly from a federal awarding agency.
Substantive Programmatic Work	The primary project activities for which award support is provided.
Supplies	Personal property other than equipment, intangible property, and debt instruments. The category of "supplies" includes items that could be considered equipment, but do not meet the threshold definition.
System for Award Management (SAM)	The System for Award Management (SAM) replaced the Central Contractor Registration (CCR) (as of July 30, 2012) and is the central government repository for organizations working with the Federal Government.
Tangible Property	Equipment, supplies, and any other property other than that defined as intangible property. It also does not include copyrights, patents, and other intellectual property that is generated or developed (rather than acquired) under an award.

Terms and Conditions of Award	All legal requirements imposed on an award by HRSA, whether based on statute, regulation, policy, or other document referenced in the NoA, or specified by the NoA itself. In addition to general terms and conditions, the NoA may include other conditions that are considered necessary to attain the award's objectives, facilitate post-award administration, conserve grant funds, or otherwise protect the Federal Government's interests.
Third-Party In-Kind Contributions	The value of non-cash contributions (i.e., property or services) that benefit a federally assisted project or program and are contributed by non-federal third parties, without charge, to a non-federal entity under a federal award. In-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.
Total Project or Program Costs	The total allowable costs (inclusive of direct **and** indirect costs) incurred by the recipient to carry out a grant-supported project or activity. Total project or program costs include costs charged to the award and costs borne by the recipient to satisfy a matching or cost-sharing requirement.
Training Project	A type of discretionary award support designed to provide student or staff training in techniques pertaining to research or the delivery of certain services.
Two-tier	Describes certain HRSA applications (usually for training grants) where the initial application submission is through Grants.gov (first tier or Phase 1) and the supplemental information submission is through the EHBs (second tier or Phase 2). Submission of EHBs information is always completed AFTER Grants.gov submission on a later date and generally at a different time (refer to FOA for specific guidance and dates).
Type 1	Brand new HRSA award. Part of a coding system used by HRSA to make distinctions between awards. The award type is the first digit of the "Award No." as indicated in Box 4a of the Notice of Award (NoA). Also see Competing Continuation (Type 2 award) and Competing Supplement (Type 3 award).

Unique Entity Identifier	Unique Entity Identifier is currently the Dun and Bradstreet Data Universal Numbering System (DUNS) number. The DUNS number is the unique entity identification number in use at HRSA. The DUNS number is required information for applicants and recipients in order to complete and maintain their registration in the System for Award Management (SAM). The Uniform Guidance references at 2 CFR § 25.315 – which describes the use of the DUNS number by federal award applicants and recipients.

This list is not all-inclusive. Please refer to 45 CFR § 75.2 Definitions.

2.7. Acronyms

AO	Authorizing Official
AOR	Authorized Organization Representative
BCRS	Bureau of Clinicial Recruitment and Service
BHPr	Bureau of Health Professions
BPHC	Bureau of Primary Health Care
BHW	Bureau of Health Workforce
CCR	Central Contractor Registration (now defunct)
CFDA	Catalog of Federal Domestic Assistance
CFR	Code of Federal Regulations
CGMO	Chief Grants Management Officer
CLAS	Culturally and Linguistically Appropriate Services
DCA	Division of Cost Allocation
DSO	Digital Services Operation
DUNS	Data Universal Numbering System
E-Biz POC	E-Business Point of Contact
EHBs	Electronic Handbooks
EIN	Employer Identification Number
EO	Executive Order
FAIN	Federal Award Identification Number
FAQ	Frequently Asked Questions
FAR	Federal Acquisition Regulation
FFATA	Federal Funding Accountability and Transparency Act
FOA	Funding Opportunity Announcement
FORHP	Federal Office of Rural Health Policy
FY	Fiscal Year
F&A	Facilities and Administration
GMO	Grants Management Officer

GMS	Grants Management Specialist
GPS	Grants Policy Statement
HAB	HIV/AIDS Bureau
HHS	Health and Human Services
HRSA	Health Resources and Services Administration
HSB	Healthcare Systems Bureau
IE	Internet Explorer
MCHB	Maternal and Child Health Bureau
MPIN	Marketing Partner ID Number
MTDC	Modified Total Direct Cost
NCC	Noncompeting Continuation
NHAS	National HIV/AIDS Strategy
NoA	Notice of Award
OFAM	Office of Federal Assistance Management
OMB	Office of Management and Budget
ORO	Office of Regional Operations
OS	Operating System
PC	Program Contact
PD	Project Director
P.L.	Public Law
PMS	Payment Management System
PO	Project Officer / Program Official
POC	Point of Contact
R&R	Research and Related
SAM	System for Award Management
SF	Standard Form
SPOC	Single Point of Contact
TA	Technical Assistance
TIN	Tax Identification Number

3. REGISTERING AND APPLYING THROUGH GRANTS.GOV

Under the two-tier system, HRSA ***requires*** you to initially apply electronically through Grants.gov. Information on validating and/or completing an application in the EHBs is provided in Section 4 of this Guide.

HRSA suggests submitting applications to Grants.gov at least three days before the deadline to allow for any unforeseen circumstances.

You are responsible for reading and complying with the Grants.gov Online User Guide, available online at http://www.grants.gov/help/html/help/index.htm. A short video on how to Register, Find and Apply is available at http://www.youtube.com/watch?v=8HLFoOoVGQY.

Grants.gov requires a one-time registration and an annual update to the registration information. **If you do not complete the registration and update it annually, you will not be able to submit an application and you will not be eligible for a deadline extension.**

The five-step registration process must be completed by every organization wishing to apply for a HRSA grant opportunity. The process will take anywhere from five business days to one month. **First-time applicants or those considering applying in the future should register immediately.** Registration with Grants.gov provides the representatives from the organization with the required credentials necessary to submit an application.

3.1. REGISTER – Applicant Organizations Must Obtain a DUNS Number and Register with SAM and Grants.gov (if not already registered)

If you have already completed Grants.gov registration for HRSA or another federal agency, confirm that it is still active and that the Authorized Organization Representative (AOR) has been approved, then skip to the next section.

The Grants.gov registration process requires information in three separate systems:

- Dun and Bradstreet (http://fedgov.dnb.com/webform/pages/CCRSearch.jsp)
- System for Award Management (SAM) (https://www.sam.gov)
- Grants.gov (http://www.grants.gov/)

You will not be able to successfully submit an application or accept an award without active and accurate information in each system.

Registration information provided in these systems is verified among the Internal Revenue System, SAM, and Grants.gov. Therefore, registration information must be consistent in each of the three systems and must be updated annually in SAM. **If you do not complete the registration and update it annually, you will not be able to submit an application in Grants.gov and you will not be eligible for a deadline extension.**

If you need to register with Grants.gov, detailed registration information can be found on Grants.gov under the APPLICANTS tab as Applicant Resources: Organization Registration (http://www.grants.gov/web/grants/applicants/organization-registration.html). These instructions will walk you through the following five basic registration steps:

Step 1: Obtain a Data Universal Numbering System (DUNS) Number
A DUNS number is a unique number that identifies an organization. It has been adopted by the Federal Government to help track how federal grant money is distributed. Ask your grant administrator or Chief Financial Officer to provide your organization's DUNS Number. An organization may have more than one DUNS Number, so ensure consistent use of the appropriate organizational DUNS Number in SAM and Grants.gov. If your organization does not have a DUNS Number, you may request one online at http://fedgov.dnb.com/webform or call the Dun & Bradstreet hotline at 1-800-705-5711 (for the U.S. and U.S. Virgin Islands) or 1-800-234-3867 (for Puerto Rico) to receive one free of charge. Once you have completed the registration, your DUNS Number will be available the same day. Note: a missing or incorrect DUNS number is the primary reason for applications being "Rejected for Errors" by Grants.gov.

Step 2: Register with the System for Award Management (SAM)
The System for Award Management (SAM) replaced the Central Contractor Registration (CCR) (as of July 30, 2012) and is the central government repository for organizations working with the Federal Government. In SAM, you must designate the organization's E-Business Point of Contact (E-Biz POC) who will create the organization's Marketing Partner ID Number (MPIN) password. The E-Biz POC will use the MPIN to designate AORs through Grants.gov.

Active SAM registration is a pre-requisite to the successful submission of grant applications!

You should monitor the following items:

- When does the SAM account expire?
- Does the organization need to complete the annual renewal of SAM registration?
- Who is the E-Business point of contact (E-Biz POC)? Is this person still with the organization?

To learn more about SAM, please visit https://www.sam.gov. View the SAM Video Tutorial for New Applicants created by the General Services Administration at http://www.youtube.com/watch?v=mmHcKCchaiY. For help using SAM, contact the Service Desk at http://www.FSD.gov.

Note: SAM information must be updated at least every 12 months to remain active (for both awardees and sub-recipients). Annual updates take a minimum of one business day to take effect in Grants.gov. Grants.gov will reject submissions from applicants with expired registrations. Do not wait until the last minute to register in SAM. As stated in the SAM Quick Start Guide for Grant Registrations (https://www.sam.gov/sam/transcript/Quick_Guide_for_Grants_Registrations.pdf),"Pleas e give yourself plenty of time before your grant application submission deadline. Allow up to 7-10 business days after you submit before your registration is active in SAM, then an additional 24 hours for Grants.gov to recognize your information." The SAM registration must be active before you can proceed to step 3. Therefore, ***check for active registration well before the application deadline.***

If you fail to allow ample time to complete registration with SAM or Grants.gov, you will not be eligible for a deadline extension or waiver of the electronic submission requirement.

Check to see if your organization is already registered at the SAM Web site. If your organization is not registered, identify the primary contact who should register your organization. Visit the SAM Web site at http://www.sam.gov to register online or call 1-888-606-8220 to register by phone. SAM Registration must be renewed annually. Before registering, you should review the SAM Registration user guide at https://www.sam.gov/sam/transcript/System_for_Award_Managementv3.3.pdf. If after having registered in SAM, you experience any registration problems, you can get help from the Federal Service Desk at https://www.fsd.gov.

You must designate the organization's E-Biz POC who will create the organization's Marketing Partner ID Number (MPIN) password. The E-Biz POC will use the MPIN to designate AORs through Grants.gov.

If your organization is registered in SAM, ensure that you renew your SAM registration yearly. If SAM registration expires, you will not be able to apply for or receive funding.

Step 3: **Creating a Username & Password**

- After the SAM registration is complete, return to Grants.gov to establish an Authorized Organization Representative (AOR). Only an AOR is authorized to submit grant applications for your organization.
- AORs must create a short profile and obtain a username and password from the Grants.gov Credential Provider.
- AORs will only be authorized for the DUNS number registered in the Grants.gov profile.

Step 4: AOR Authorization

- The E-Biz POC uses the DUNS number and MPIN to authorize your AOR status.
- Only the E-Biz POC may authorize AORs.
- Only approved/authorized AORs may submit on behalf of an organization.
- AORs that have not been approved by the E-Biz POC will not be able to submit applications through Grants.gov.

Step 5: Track AOR Status

- Using your username and password from Step 3, go to Grants.gov under Applicant Login to check your AOR status at https://apply07.grants.gov/apply/login.faces.

Allow for extra time if you do not have a Tax Identification Number (TIN) or Employer Identification Number (EIN). SAM validates the EIN against Internal Revenue Service records, a step that will take an additional one to five business days.

Additional assistance with the registration process is available at Grants.gov under ORGANIZATION REGISTRATION at http://www.grants.gov/web/grants/applicants/organization-registration.html. In addition, under APPLICANT RESOURCES at http://www.grants.gov/web/grants/applicants.html a variety of support options are available including FAQs, Glossary, Online User Guide & Checklists, Training, General Support, and Technical Support.

Please direct questions regarding Grants.gov registration to the Grants.gov Call Center at 1-800-518-4726 (International callers, please dial 606-545-5035). Call Center hours of operation are 24 hours a day, 7 days a week, excluding federal holidays. You may also receive assistance via email at support@grants.gov or access the Grants.gov Self-Service Knowledge Base at https://grants-portal.psc.gov/Welcome.aspx.

- **NOTE:** It is HIGHLY recommended that this registration process is completed at least TWO WEEKS prior to the submittal date of your organization's first Grants.gov submission.

3.2. APPLY - Apply through Grants.gov

Grants.gov includes a simple, unified application process to enable you to apply for grants online. The information you need to register and submit your application online can be found at Grants.gov under the APPLICANTS *tab* under *Apply for Grants* (http://www.grants.gov/web/grants/applicants/apply-for-grants.html). The site also contains an *Online User Guide* athttp://www.grants.gov/help/html/help/index.htm.

The application will be one of three announcement types indicated on the cover of the FOA: new, competing continuation, or competing supplement. All competing

applications are initially submitted electronically to HRSA through Grants.gov using the Application for Federal Assistance SF-424 R&R application.**

If you are applying for awards that require the SF-424 Non-Construction application package, you must refer to HRSA's *SF-424 Two-Tier Application Guide* at http://www.hrsa.gov/grants/apply/applicationguide/sf424programspecificappguide.pdf for guidance. If you are applying for awards that do **not** require supplemental information submission through the Electronic Handbooks, you must refer to HRSA's *SF-424 R&R Application Guide* at **http://www.hrsa.gov/grants/apply/applicationguide/sf424rrguidev2.pdf.**

3.2.1. Find Funding Opportunity

If you are submitting a competing application, you may search for the announcement in Grants.gov by clicking the SEARCH GRANTS tab (http://www.grants.gov/web/grants/search-grants.html), entering the FOA number and then selecting the announcement for which you wish to apply.. Refer to the FOA for eligibility criteria.

If you are an existing awardee and are submitting a competing continuation or competing supplement application, search for the announcement under the APPLICANTS tab under *Apply for Grants* (http://www.grants.gov/web/grants/applicants/apply-for-grants.html). Enter the announcement number provided in the field, Funding Opportunity Number. (Example announcement number: HRSA-16-001.)

3.2.2. Download Application Package

Download the application package and instructions. Application packages are posted in Adobe Reader format. To ensure that you can view the application package and instructions, you should download and install the Adobe Reader application. The application package will be saved to your computer, completed offline, and then uploaded to Grants.gov at the time of submission.

For more information on using Adobe Reader, refer to Section 9.1.2.

- **NOTE:** Please review the system requirements for Adobe Reader at http://www.grants.gov/web/grants/applicants/adobe-software-compatibility.html.

3.2.3. Complete the Grant Application Package

Complete Phase 1, the Grants.gov portion of the application using both the built-in instructions and the instructions provided in the FOA. You may complete the application offline – you are not required to be connected to the Internet. Ensure that you save a copy of the application on your computer. For assistance with program guidance related questions, please contact the Program Contact (PC) listed in Section VII of the FOA. For assistance with budget or other administrative related questions, please contact the Grants Management Specialist (GMS) listed in Section VII of the FOA.

- **NOTE:** Awardees with competing continuations and competing supplements should provide their 10-digit grant number [box 4b from the NoA] in the Federal Identifier field (box 4.a. in SF-424 R&R).

3.2.4. Submit a Completed Application Package

Once you have downloaded the application package, completed all required forms, and attached all required documents—click the "Check Package for Errors" button and make any necessary corrections.

- In Adobe Reader, click on the "Save and Submit" button when you have done all of the above and are ready to send your completed application to Grants.gov.

Review the provided application summary to confirm that the application will be submitted to the program for which you wish to apply. **If you submit an application to the wrong announcement number, you must apply to the correct announcement number on or before the posted deadline**. To submit, **the AOR** must login to Grants.gov and enter their username and password. Note: the same DUNS number, AOR username, and password must be used to complete and submit your application. Once you have logged in, your application package will automatically be uploaded to Grants.gov. A confirmation screen will appear once the upload is complete. Note that a Grants.gov Tracking Number will be provided on this screen (GRANTXXXXX). Please record this number so that you may refer to it for all subsequent help.

Please direct questions regarding application submission to the Grants.gov Call Center at: 1-800-518-4726 (International callers, please dial 606-545-5035). Call Center hours of operation are 24 hours a day, 7 days a week, excluding federal holidays.

- **NOTE:** The AOR must be connected to the Internet and must have a Grants.gov username and password tied to the correct DUNS number in order to submit the application package.

3.2.5. Verify Status of Application in Grants.gov

Once Grants.gov has received your submission, Grants.gov will send email messages to the Project Director (PD), Authorized Organizational Representative (AOR), and the Point of Contact (POC) listed in the application advising of the progress of the application through the system. You will receive up to four emails. The first will confirm receipt of your application by the Grants.gov system ("Received"), and the second will indicate that the application has either been successfully validated ("Validated") by the system prior to transmission to the grantor agency or has been rejected due to errors ("Rejected with Errors"). **An application for HRSA funding must be both received and validated by Grants.gov by the application deadline.**

Upon submission, Grants.gov will attempt to validate the application. This validation ensures that the AOR has submitted the application and that all required standard forms are complete and have the correct type of information in them. Grants.gov will also validate that your SAM registration is current. Grants.gov will not validate application content, attachments, page limit, or your organization's eligibility.

If your application has been rejected due to an error, you must correct the application and resubmit it to Grants.gov before the posted deadline. The full verification process may take hours to days, therefore, you need to allow plenty of time. If you are unable to resubmit because the opportunity has since closed, you must follow the instructions in **Section 3.6** to request a waiver.

You can check the status of your application(s) any time after submission by visiting Grants.gov's Track My Application page at http://www.grants.gov/web/grants/applicants/track-my-application.html. This link will also be included in the confirmation email that you receive from Grants.gov.

If there are no errors, the application will be downloaded by HRSA. Upon successful download to HRSA, the status of the application will change to "Received by Agency" and the contacts listed in the application will receive a third email from Grants.gov. Once your application is received by HRSA, it will be processed to ensure that the application is submitted for the correct funding announcement, with the correct grant number (if applicable), and applicant/grantee organization. Upon this processing, which is expected to take up to two to three business days, HRSA will assign a unique tracking number to your application. This tracking number will be posted to Grants.gov and the status of your application will be changed to "Agency Tracking Number Assigned." You will receive the fourth email in which Grants.gov will provide the Agency Tracking Number. Record the HRSA tracking number and use it for all correspondence with HRSA.

3.3. Receipt Acknowledgement

In summary, upon receipt of an application, Grants.gov will send a series of email messages to document the progress of an application through the system.

1) The first will confirm receipt in the system;
2) The second will indicate whether the application has been successfully validated or has been rejected due to errors;
3) The third will be sent when the application has been successfully downloaded at HRSA; and
4) The fourth will notify you of the Agency Tracking Number assigned to the application.

If you are trying to track your application and you have not received any emails from Grants.gov, be sure to check your spam folder. Sometimes the emails from Grants.gov are blocked by your email service.

After successful submission in Grants.gov (Phase 1) and subsequent processing by HRSA, you will be notified by HRSA confirming the successful receipt of your application and the requirements for the Project Director and Authorizing Official to review and submit additional information in the HRSA's EHBs (Phase 2). Your application will not be considered compliant and complete unless you review and submit the additional information in HRSA's EHBs by the due date.

Notifications from HRSA EHBs are expected to go out within 7 business days from the date of submission. If you do not receive notification that your application has been successfully received, please contact the HRSA EHBs Contact Center at 877-GO4-HRSA (877-464-4772) [TTY: (877) 897-9910] Monday through Friday between 8:00 a.m. and 8:00 p.m. ET or via the web at http://www.hrsa.gov/about/contact/ehbhelp.aspx. Please have your Grants.gov tracking number available.

3.4. Tracking Your Application

It is incumbent on you to track your application by using the Grants.gov tracking number (GRANTXXXXXXXX) provided in the confirmation email from Grants.gov. More information about tracking an application can be found at http://www.grants.gov/web/grants/applicants/track-my-application.html. Be sure the application is validated by Grants.gov (under the correct funding opportunity number) prior to the application deadline.

3.5. Late Applications

Applications which do not meet the criteria as outlined in Section IV of the FOA will be considered late applications and will not be considered in the current competition.

3.6. Requesting a Waiver from the Electronic Submission Requirement

HRSA ***requires*** you to apply electronically through Grants.gov and have the application validated under the correct funding opportunity number on or before the deadline date and time. The registration and application process protects you against fraud and ensures that only authorized representatives from an organization can submit an application. You are responsible for maintaining these registrations, which should be completed well in advance of submitting an application. You ***must*** submit in this manner unless they obtain a written exemption from this requirement, within five days of the opportunity's closing date, by the Director of HRSA's Division of Grants Policy.

You must request an exemption in writing from **DGPWaivers@hrsa.gov**, and provide details as to why you are technologically unable to submit electronically through the Grants.gov portal. If requesting a waiver from the electronic submission requirements, include the following in the e-mail request: the HRSA announcement number for which the organization is seeking relief; the organization's name, address, and telephone number; the organization's DUNS number; the name, address, and telephone number of the PD; as well as the Grants.gov Tracking Number (GRANTXXXXXXXX) assigned to the submission along with a copy of the "Rejected with Errors" notification as received from Grants.gov, if applicable. If case numbers were given from calling Grants.gov, please include those as well. HRSA's Division of Grants Policy is the only office authorized to grant waivers.

HRSA and its Digital Services Operation (DSO) will only accept paper applications from applicants that received prior written approval. However, the application must still be submitted by the deadline. Suggestion: submit application to Grants.gov at least three days before the deadline to allow for any unforeseen circumstances.

HRSA is very strict on adhering to application deadlines and electronic submission requirements. Deadline extensions will not be granted for Grants.gov verification errors, last-minute registration, or submission errors on your part. The CGMO or designee may consider an extension of published deadlines or allowance of a submission outside of the Grants.gov system, when justified by circumstances such as natural disasters (e.g., floods or hurricanes), other disruptions of services, such as a prolonged blackout, or in the rare event of a validated technical issue on the side of the government that prevented you from applying before the deadline. The CGMO or designee will determine the affected geographical area(s).

4. VALIDATING AND/OR COMPLETING AN APPLICATION IN THE HRSA ELECTRONIC HANDBOOKS (EHBs)

4.1. Register - Project Director and Authorizing Official Must Register with HRSA EHBs (if not already registered)

To access a competing application in HRSA EHBs, you must register within the EHBs. The purpose of the registration process is to collect consistent information from all applicants and allow for the unique identification of each system user.

- **Registration within HRSA EHBs is required only once for each applicant.**
- **HRSA EHBs now allow a single username to be associated with more than one organization.**

Registration within HRSA EHBs is a two-step process. In the first step, individual users from an organization who participate in the application process must create **individual** system accounts. In the second step, the users must associate themselves with the appropriate grantee organization. **To find your organization's record, use the DUNS number associated with the application submitted in Grants.gov.**

To complete the HRSA EHBs registration:

1. Create Individual User Accounts: Identify your role in the grants management process. HRSA EHBs offer the following three functional roles for individuals from applicant/awardee organizations:

   - Authorizing Official (AO),
   - Business Official (BO), and
   - Other Employee (for Project Directors, assistant staff, AO designees and others).

   For more information on functional responsibilities, refer to the HRSA EHBs online help.

2. Associate user with Applicant Organization: Locate the DUNS number from the application SF-424 submitted through Grants.gov. You must use this number to find your organization during registration. All individuals from the organization working on the application must use the same DUNS number to ensure correct registration.

Registration with HRSA EHBs is independent of Grants.gov registration.

For assistance in registering with HRSA EHBs, call the HRSA EHBs Contact Center at 1-877-464-4772 [TTY: 877-897-9910], Monday through Friday (except federal holidays) from 8:00 a.m. to 8:00 p.m. ET or via the web at http://www.hrsa.gov/about/contact/ehbhelp.aspx.

- **IMPORTANT:** You must use your HRSA EHBs Tracking Number or your 10-digit grant number (box 4b from NoA) to identify your organization.

4.2. Verify Status of Application

HRSA will send an email to the PD, AO, POC, and the BO (listed on the submitted application) to confirm that the application was successfully received.

- **NOTE:** You should check HRSA EHBs within two to three business days after submission through Grants.gov for availability of your application.

4.3. Validate Grants.gov Application in the HRSA EHBs

The HRSA EHBs include a validation process to ensure that only authorized individuals from an organization are able to access the organization's competing applications. The first user who seeks access to any competing application will need to provide the following information:

Data Element	Source	Example
Announcement Number	From submitted Grants.gov application	HRSA-FY-###
Grants.gov Tracking Number	From submitted Grants.gov application	GRANTXXXXXXXX
HRSA EHBs Application Tracking Number	From email notification sent to PD, AO, BO, and POC listed on application.	123456

Note that the source of each data element is different and knowledge of the three numbers together is considered sufficient to provide that individual access to the application.

To validate the Grants.gov application, log in to the EHBs and click on the *View Applications* link and then click on the *Add Grants.Gov Application* link. (This is only visible for grant applications that require supplemental forms.)

You will now need to complete a form using the numbers specified in the table above to validate your Grants.gov application.

- **NOTE:** The first individual who completes this step should use the "Peer Access" feature to share the application with other individuals from the organization. It is recommended that the AO complete this step.

4.4. Manage Access to the Application

You must be registered in HRSA EHBs to access the application. To ensure that only authorized individuals from the organization gain access to the application, you must follow the process described earlier.

The individual who validated the application must use the "Peer Access" feature to share this application with other individuals from the organization. This is required if you wish to allow multiple individuals to work on the application in HRSA EHBs.

Once you have access to the EHBs for your specific application, use the appropriate link under the deliverables section to access your grant application.

4.5. Check Validation Errors

HRSA EHBs will validate the application received through Grants.gov. All validation errors are recorded and displayed to you. To view the validation errors use the *Grants.gov Data Validation Comments* link on the application status page in HRSA EHBs.

4.6. Fix Errors and Complete Application

You must review the errors in HRSA EHBs and make necessary corrections. You must also complete the detailed budget and other required forms in HRSA EHBs and assign an AO who must be a registered user in the HRSA EHBs. HRSA EHBs will show the status of each form in the application package and the status of all forms must be "Complete" in the summary page before the HRSA EHBs will allow the application to be submitted.

4.7. Submit Application in HRSA EHBs

4.7.1. Competing Applications Submitted Using Both Grants.gov and HRSA EHBs

After the Grants.gov application is pulled into EHBs and validated, the AO verifies the pending application in HRSA EHBs, and fixes any validation errors. Supplemental application forms and any required attachments are completed. The application must then be submitted by the AO assigned to the application within HRSA EHBs. (The

designee of the AO can also submit the application.) The completed application must be submitted to HRSA by the due dates listed within the FOA.

- **NOTE:** You must submit the application by the due date listed within the FOA. There are two deadlines within the announcement – one for submission within Grants.gov and the second for submission within HRSA EHBs. You may not complete the EHBs portion if the Grants.gov deadline is not met.

Performance Measures for Competitive Applications - Some HRSA FOAs include specific data forms and require performance measure reporting. If the completion of performance measure information is indicated in the FOA, successful applicants receiving grant funds will be required, within 30 days of the Notice of Award (NoA) to register in EHBs and electronically complete the program-specific data forms that appear in this announcement. This requires the provision of budget breakdowns in the financial forms based on the grant award amount, the project abstract and other grant summary data, and objectives for the performance measures.

5. GENERAL INSTRUCTIONS FOR APPLICATION SUBMISSION

HRSA ***requires*** you to apply electronically through Grants.gov. You must download the Standard Form 424 Research and Related (SF-424 R&R) application package associated with the FOA following the directions provided at Grants.gov.

The following instructions are applicable to all submissions unless otherwise noted in the relevant FOA. Failure to follow the instructions may make your application non-responsive. Non-responsive applications will not be given any consideration and the particular applicants will be notified. It is mandatory to follow the instructions provided to ensure that your application can be printed efficiently and consistently for review.

5.1. Instructions for Completing the SF-424 R&R for two-tier applications

i. Application Face Page

Complete Application Form SF-424 R&R short form provided with the application package. Prepare according to instructions provided in the form itself.

DUNS Number

Your organization (and subrecipients of HRSA award funds) is required to have a DUNS number in order to apply for a grant or cooperative agreement from the Federal Government. Please include the DUNS number in form SF-424 R&R - item 5 on the application face page. Applications ***will not*** be reviewed without a DUNS number. Note: A missing or incorrect DUNS number is the number one reason for applications being "Rejected for Errors" by Grants.gov. HRSA will not extend the deadline for applications with a missing or incorrect DUNS number. You should take care in entering the DUNS number in the application.

Additionally, your organization (and any subrecipient of HRSA award funds) is required to register annually with SAM in order to conduct electronic business with the Federal Government. SAM registration must be maintained with current, accurate information at all times during which an entity has an active award or an application or plan under consideration by HRSA. It is extremely important to verify that your organization's SAM registration is active and the Marketing Partner ID Number (MPIN) is current. Information about registering with SAM can be found at https://www.sam.gov.

CFDA Number

The Catalog of Federal Domestic Assistance (CFDA) Number, as listed on the cover of the FOA, is prepopulated in box 10 of the form.

ii. Intergovernmental Review (Executive Order (EO) 12372)

If an FOA is subject to EO 12372, "Intergovernmental Review of federal Programs," or not it will be stated in Section IV.5. Intergovernmental Review. Please refer to #16 on the SF-424 R&R.

If intergovernmental review applies, the following language will appear in the FOA:

> PROGRAM NAME is a program subject to the provisions of Executive Order (EO) 12372, as implemented by 45 CFR part 100. See Executive Order 12372 in the HHS Grants Policy Statement.

EO12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain federal programs. Application packages made available under this FOA will contain a listing of States which have chosen to set up such a review system, and will provide a State Single Point of Contact (SPOC) for the review. Information on States affected by this program and SPOCmay also be obtained from the following Web site: http://www.whitehouse.gov/omb/grants_spoc.

All applicants other than federally recognized Native American tribes or tribal organizations should contact their SPOC as early as possible to alert them to the prospective applications and receive any necessary instructions on the state's process used under this EO.

iii. Table of Contents

The application should be presented in the order of the Table of Contents provided in Section 5.3 of this *SF-424 R&R Two-Tier Application Guide*. Again, for electronic applications no table of contents is necessary as it will be generated by the system. (Note: the Table of Contents will not be counted in the page limit.)

iv. Budget

Note: the directions here may differ from those offered by Grants.gov. Please follow the instructions included in the program-specific FOA and the instructions below when completing budget forms.

Reminder: The Total Project or Program Costs are the total allowable costs (inclusive of direct **and** indirect costs) incurred by the recipient to carry out a HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by the recipient to satisfy a matching or cost-sharing requirement, as applicable.

Classification of Costs:
There is no universal rule for classifying certain costs as either direct or indirect (F&A) under every accounting system. A cost may be direct with respect to some specific service or function, but indirect with respect to the federal award or other final cost objective. Therefore, it is essential that each item of cost incurred for the same purpose be treated consistently in like circumstances either as a direct or an indirect (F&A) cost in order to avoid possible double-charging of federal awards. Guidelines for determining direct and indirect (F&A) costs charged to federal awards are provided in 45 CFR part 75, subpart E.

Research & Related Budget:
Please complete the Research & Related Budget form included with the application package (Sections A – J and the Cumulative Budget) for each budget period. While up to five budget periods are available on the form, refer to the grant specific guidelines for the maximum number of budget periods allowed in the grant program for which you are applying. Following completion of Budget Period 1, click on the "NEXT PERIOD" button on the final page to allow for completion of Budget Period 2. Repeat this instruction to complete any remaining Budget Periods.

The Cumulative Budget is automatically generated and provides the total budget information for the grant request. Errors found in the Cumulative Budget must be corrected within the incorrect field(s) in all Budget Periods; corrections cannot be made to the Cumulative Budget itself.

If the FOA notes that the program is subject to the General Provisions of P.L. 114-113, the following Salary Limitation applies:

Salary Limitation:
The General Provisions in Division H, § 202, of the Consolidated Appropriations Act, 2016 (P.L. 114-113), includes provisions for a salary rate limitation. The law limits the salary amount that may be awarded and charged to HRSA grants and cooperative agreements. Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II. The Executive Level II salary of the Federal Executive Pay scale is $185,100 . This amount reflects an individual's base salary exclusive of fringe and any income that an individual may be permitted to earn outside of the duties to your organization. This salary limitation also applies to subrecipients under a HRSA grant or cooperative agreement. Note that these or other salary limitations will apply in FY 2017, as required by law.

As an example of the application of this limitation: If an individual's base salary is $255,000 per year plus fringe benefits of 25% ($63,750) and that individual is devoting 50%/half of their time to this award, their base salary should be adjusted to $185,100 plus fringe at 25% of half this amount ($23,137.50) and a total of $115,687.50 may be included in the project budget and charged to the award for salary/fringe benefits for that individual. See the breakdown below:

Individual's *actual* base full time salary: $255,000 50% of time will be devoted to project	
Direct salary	$127,500
Fringe (25% of salary)	$31,875
Total	$159,375
Amount that may be claimed on the application budget due to the legislative salary limitation: Individual's base full time salary *adjusted* to Executive Level II: $185,100 50% of time will be devoted to the project	
Direct salary	**$92,550**
Fringe (25% of salary)	**$23,137.50**
Total amount	**$115,687.50**

Funding Restrictions (in general)
You may request no more than the ceiling amount listed in Section II.2. Summary of Funding and Section IV.6. Funding Restrictions of the FOA. Awards to support projects will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that funding would be in the best interest of the Federal Government.

The governing cost principles address selected items of cost. The FOA specifies unallowable costs that apply to each funding opportunity. The following list of unallowable costs is not intended to be all-inclusive. The cost principles should be consulted for the complete explanation of the allowability or unallowability of costs they address. For the full list of cost principles refer to Section 2.3 "Compliance Requirements at a Glance" to see which cost principles apply to your organization and refer to to Subpart E – Cost Principles at 45 CFR part 75. The allowability of costs under individual HRSA awards also may be governed by requirements specified in the program legislation, regulations, or the specific terms and conditions of the award, which will take precedence over the general information provided here.

Item	Description
Advertising and Public Relations	Conditionally allowable. See 45 CFR § 75.421 for details.
Advisory Councils	Costs incurred by advisory councils or committees are unallowable **unless** authorized by statute, the HHS awarding agency or as an indirect cost where allocable to federal awards. See 45 CFR § 75.444, applicable to states, local governments and Indian Tribes.
Alcoholic Beverages	Unallowable as an entertainment expense.

Bad Debts	Unallowable.
Entertainment Costs	Conditionally unallowable. This includes the cost of amusements, social activities, and related incidental costs. 45 CFR § 75.438 clarifies when entertainment costs may be charged to a federal award with prior approval.
Fundraising Costs	Unallowable.
Honoraria	Unallowable when the primary intent is to confer distinction on, or to symbolize respect, esteem, or admiration for, the recipient of the honorarium. A payment for services rendered, such as a speaker's fee under a conference grant, is allowable.
Invention, Patent, or Licensing Costs	Unallowable as a direct cost unless specifically authorized in the NoA. May be allowable as indirect costs provided they are authorized under applicable cost principles and are included in the negotiation of indirect cost rates. Such costs include licensing or option fees, attorney's fees for preparing or submitting patent applications, and fees paid to the U.S. Patent and Trademark Office for patent application, patent maintenance, or recordation of patent-related information.
Lobbying	Generally unallowable, including costs of lobbying activities to influence the introduction, enactment, or modification of legislation by the U.S. Congress or a state legislature. Under certain circumstances, as provided in the applicable cost principles, costs associated with activities that might otherwise be considered "lobbying" that are directly related to the performance of a grant or cooperative agreement may be allowable. The recipient should obtain an advance understanding with the GMS if it intends to engage in these activities. See "Restriction on Lobbying" below and at 45 CFR § 75.450 for additional descriptions and examples of prohibited activities. View a webinar on "The Ins and Outs of Lobbying for HRSA Grantees" at http://services.choruscall.com/links/hrsa141028.html.
Meals	Generally unallowable except for the following: • Subjects and patients under study • Where specifically approved as part of the project or program activity, e.g., in programs providing children's services • When an organization customarily provides meals to employees working beyond the normal workday, as a part of a formal compensation arrangement

	• As part of a per diem or subsistence allowance provided in conjunction with allowable travel. • Under a conference grant, when meals are a necessary and integral part of a conference, provided that meal costs are not duplicated in participants' per diem or subsistence allowances. Guest meals are not allowable. (See "Consumer/Provider Board Participation" in Definitions section regarding the allowability of the cost of meals for consumer and provider board participants in federal award-supported activities.)
Pre-award Costs	Costs incurred prior to the effective date of the sponsored agreement, whether or not they would have been allowable thereunder if incurred after such date, are unallowable unless approved by the federal agency or authorized under expanded authority. Where authorized by the sponsoring agency as an expanded authority, a recipient may, at its own risk and without sponsoring agency prior approval, incur obligations and expenditures to cover costs up to (and including) 90 days before the beginning date of the initial budget period of a new or competing continuation award if such costs • are necessary to conduct the project or program, and • would be allowable under the grant or cooperative agreement, if awarded. However, even if authorized as an expanded authority, if a specific expenditure would otherwise require prior approval, the cost or activity must meet the same tests of allowability as if incurred after award. If not authorized as part of expanded authorities, the applicant/recipient must seek sponsoring agency prior approval before incurring pre-award costs. Sponsoring agency prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or competing continuation award.
Promotional Items (SWAG)	Promotional items and memorabilia (SWAG e.g., pencils, cups, t-shirts, cookbooks, bags, etc.), gifts, and souvenirs designed to promote the recipient's organization are unallowable as advertising/public relations costs.

Funding Restrictions: If the FOA notes that the program is subject to the General Provisions of P.L. 114-113, the following legislative mandates are in effect:

1. Salary Limitation (Section 202)
2. Gun Control (Section 210)
3. Anti-Lobbying (Section 503)
4. Acknowledgment of Federal Funding (Section 505)
5. Restriction on Abortions (Section 506)
6. Exceptions to Restriction on Abortions (Section 507)
7. Ban on Funding Human Embryo Research (Section 508)
8. Limit on Use of Funds for Promotion of Legalization of Controlled Substances (Section 509)
9. Dissemination of False or Misleading Information (Section (515(b))
10. Restriction on Distribution of Sterile Needles (Section 520)
11. Restriction of Pornography on Computer Networks (Section 521)
12. Restriction on Funding ACORN (Section 522)

Details:

1. Salary Limitation (Section 202)

   "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II."

   The Executive Level II salary increased to $185,100 effective January 10, 2016.

   This amount reflects an individual's base salary exclusive of fringe and any income that an individual may be permitted to earn outside of the duties to the applicant organization. This salary limitation also applies to subawards/subcontracts under an HRSA grant or cooperative agreement.

2. Gun Control (Section 210)

   “None of the funds made available in this title may be used, in whole or in part, to advocate or promote gun control.”

3. Anti-Lobbying (Section 503)

   “ (a) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111–148 shall be used, other than for normal and recognized executive legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself.

   (b) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111–148 shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government.

   (c) The prohibitions in subsections (a) and (b) shall include any activity to advocate or promote any proposed, pending or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control."

4. Acknowledgment of Federal Funding (Section 505)

   "When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all grantees receiving Federal funds included in this Act, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state – (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources."

5. Restriction on Abortions (Section 506)

   “(a) None of the funds appropriated in this Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for any abortion.

   (b) None of the funds appropriated in this Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for health benefits coverage that includes coverage of abortion.

   (c) The term ‘‘health benefits coverage’’ means the package of services covered by a managed care provider or organization pursuant to a contract or other arrangement.”

6. Exceptions to Restriction on Abortions (Section 507)

   “(a) The limitations established in the preceding section shall not apply to an abortion – (1) if the pregnancy is the result of an act of rape or incest; or (2) in the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.

(b) Nothing in the preceding section shall be construed as prohibiting the expenditure by a State, locality, entity, or private person of State, local, or private funds (other than a State's or locality's contribution of Medicaid matching funds).

(c) Nothing in the preceding section shall be construed as restricting the ability of any managed care provider from offering abortion coverage or the ability of a State or locality to contract separately with such a provider for such coverage with State funds (other than a State's or locality's contribution of Medicaid matching funds).

(d)(1) None of the funds made available in this Act may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.

(d)(2) In this subsection, the term ''health care entity'' includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan."

7. Ban on Funding of Human Embryo Research (Section 508)

"(a) None of the funds made available in this Act may be used for – (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(b) For purposes of this section, the term ''human embryo or embryos'' includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

8. Limitation on Use of Funds for Promotion of Legalization of Controlled Substances (Section 509)

   "(a) None of the funds made available in this Act may be used for any activity that promotes the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established under section 202 of the Controlled Substances Act except for normal and recognized executive-congressional communications.

   (b)The limitation in subsection (a) shall not apply when there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage."

9. Dissemination of False or Deliberately Misleading Scientific Information (Section 515(b))

   “None of the funds made available in this Act may be used to disseminate information that is deliberately false or misleading.”

10. Restriction on Distribution of Sterile Needles (Section 520)

    "Notwithstanding any other provision of this Act, no funds appropriated in this Act shall be used to purchase sterile needles or syringes for the hypodermic injection of any illegal drug: Provided, That such limitation does not apply to the use of funds for elements of a program other than making such purchases if the relevant State or local health department, in consultation with the Centers for Disease Control and Prevention, determines that the State or local jurisdiction, as applicable, is experiencing, or is at risk for, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use, and such program is operating in accordance with State and local law.”

11. Restriction of Pornography on Computer Networks (Section 521)

"(a) None of the funds made available in this Act may be used to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

(b) Nothing in subsection (a) shall limit the use of funds necessary for any Federal, State, tribal, or local law enforcement agency or any other entity carrying out criminal investigations, prosecution, or adjudication activities."

12. Restrictions on Funding ACORN (Section 522)

"None of the funds made available under this or any other Act, or any prior Appropriations Act, may be provided to the Association of Community Organizations for Reform Now (ACORN), or any of its affiliates, subsidiaries, allied organizations, or successors."

v. Budget Justification Narrative

Upload the Budget Justification Narrative for the entire project period (**all** budget periods) in Section K of the Research & Related Budget Form. Provide a budget narrative that explains the amounts requested for each line of the budget in Sections A-F. The budget narrative should specifically describe how each item will support the achievement of proposed objectives. Be very careful about showing how each item in the "other" category is justified. For subsequent budget years, the narrative should highlight the changes from year one or clearly indicate that there are no substantive budget changes during the project period. Do NOT use the budget narrative to expand the project narrative.

Budget for Multi-Year Award (project periods vary, maximum of five years)

FOAs invite applications for project periods of one to up to five years. Generally, awards, on a competitive basis, will be for a one-year budget period; although the project period may be up to five years. Submission and HRSA approval of the Progress Report(s) and any other required submission or reports is the basis for the budget period renewal and release of subsequent year funds. Funding beyond the one-year budget period but within the multi-year project period is subject to availability of funds, satisfactory progress of the awardee, and a determination that continued funding would be in the best interest of the Federal Government.

In addition to requirements included in the program-specific FOA, include the following in the Budget Justification narrative:

Personnel Costs (as listed in Sections A & B on the R&R Budget Form): Personnel costs should be explained by listing each staff member who will be supported from funds, name (if possible), position title, percentage of full-time equivalency, and annual salary. If the FOA notes that the program is subject to the General Provisions of P.L. 114-113, the following applies: Reminder: Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II or $185,100. An individual's base salary, per se, is NOT constrained by the legislative provision for a limitation of salary. The rate limitation simply limits the amount that may be awarded and charged to HRSA grants and cooperative agreements. Please provide an individual's actual base salary if it exceeds the cap. See the sample below.

Sample:

Name	Position Title	% of FTE	Annual Salary	Amount Requested
J. Smith	Chief Executive Officer	50	$185,100*	$92,550
R. Doe	Nurse Practitioner	100	$75,950	$75,950
D. Jones	Data/AP Specialist	25	$33,000	$8,250

*Actual annual salary = $255,000

Fringe Benefits (as listed in Sections A & B on the R&R Budget Form): List the components that comprise the fringe benefit rate, for example health insurance, taxes, unemployment insurance, life insurance, retirement plans, and tuition reimbursement. The fringe benefits should be directly proportional to that portion of personnel costs that are allocated for the project. If the FOA notes that the program is subject to the General Provisions of P.L. 114-113, the following applies: If an individual's base salary exceeds the legislative salary cap (i.e., $185,100), please adjust fringe proportionally.

Equipment (as listed in Section C on the R&R Budget Form): List equipment costs and provide justification for the need of the equipment to carry out the project's goals. Extensive justification and a detailed status of current equipment must be provided when requesting funds for the purchase of items that meet the definition of equipment (a unit cost of $5,000 or more and a useful life of one or more years).

Travel (as listed in Section D on the R&R Budget Form): List travel costs according to local and long distance travel. For local travel, the mileage rate, number of miles, reason for travel and staff member/consumers completing the travel should be outlined. Include travel expenses (e.g., airfare, lodging, parking, per diem, etc.) for each person and trip associated with participating in meetings and other proposed trainings or workshops. Name the traveler(s) if possible,

describe the purpose of the travel, provide number of trips involved, the destinations, and the number of individuals for whom funds are requested.

Participant/Trainee Support Costs, if applicable (as listed in Section E on the R&R Budget Form): List tuition/fees/health insurance, stipends, travel, subsistence, other and the number of participants/trainees.

Other Direct Costs (as listed in Section F on the R&R Budget Form) include the following, if applicable:

Materials and Supplies: List the items that the project will use to implement the proposed project. Separate items into three categories: office supplies (e.g., paper, pencils), medical supplies (e.g., syringes, blood tubes, gloves), and educational supplies (e.g., brochures, videos). Remember, they must be listed separately.

Per Subpart D 2 CFR § 200.314 (as codified by HHS at 45 CFR § 75.321), Property will be classified as supplies if the acquisition cost is under $5,000. Note that items such as laptops, tablets, and desktop computers are classified as a supply if the value is under the $5,000 equipment threshold.

Publication Costs: List the total publication funds requested. The proposal budget may request funds for the costs of documenting, preparing, publishing or otherwise making available to others the findings and products of the work conducted under the award. In the budget justification include supporting information.

Consultant Services: List the total costs for all consultant services. In the budget justification, identify each consultant, the services he/she will perform, total number of days, travel costs, and total estimated costs.

ADP/Computer Services: List total funds requested for ADP/Computer Services. The cost of computer services, including computer-based retrieval of scientific, technical and education information may be requested. In the budget justification, include the established computer service rates at the proposing organization if applicable.

Subawards/Consortium/Contractual Costs: Provide a clear explanation as to the purpose of each subaward/contract, how the costs were estimated, and the specific contract deliverables. Applicants are responsible for ensuring that their organization or institution has in place an established and adequate procurement system with fully developed written procedures for awarding and monitoring all contracts. Reminder: recipients must notify potential subrecipients that entities receiving subawards must be registered in SAM and provide the recipient with their DUNS number.

Per the Suspension and Debarment rules in the Uniform Guidance, as implemented by HRSA at 45 CFR § 75.212, non-federal entities and contractors are subject to the non-procurement debarment and suspension regulations implementing Executive Orders 12549 and 12689, 2 CFR parts 180 and 376. These regulations restrict awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in federal assistance programs or activities.

Equipment or Facility Rental/User Fees: List total funds requested for Equipment or Facility Rental/Use Fees. In the budget justification, identify each rental user fee and justify.

Alterations and Renovations: List total funds requested for Alterations & Renovations. In the budget justification, itemize, by category and justify the costs of alterations and renovations including repairs, painting, removal or installation of partitions, shielding, or air conditioning. Where applicable, provide the square footage and costs.

Other: Put all costs that do not fit into any other category into this category and provide an explanation of each cost in this category. In some cases, rent, utilities and insurance fall under this category if they are not included in an approved indirect cost rate.

You may include the cost of access accommodations as part of their project's budget, including sign interpreters, plain language and health literate print materials in alternate formats (including Braille, large print, etc.); and cultural/linguistic competence modifications such as use of cultural brokers, translation or interpretation services at meetings, clinical encounters, and conferences, etc.

Data Collection Activities: Funds may be used to support appropriate and justifiable costs related to meeting evaluation and reporting requirements. Identify and justify how these funds will be used under the appropriate budget category (personnel, contractual or other).

Indirect Costs: Indirect costs are those costs incurred for common or joint objectives which cannot be readily and specifically identified with a particular project or program but are necessary to the operations of the organization, e.g., the cost of operating and maintaining facilities, depreciation, and administrative salaries. For some institutions, the term "facilities and administration" is used to denote indirect costs. If your organization does not have an indirect cost rate, you may wish to obtain one through HHS's Division of Cost Allocation (DCA). Visit DCA's website at https://rates.psc.gov/ to learn more about rate agreements, the process for applying for them, and the regional offices which

negotiate them. If indirect costs are included in the budget, please attach a copy of the indirect cost rate agreement. If the indirect cost rate agreement is required per the FOA, it will not count toward the page limit. Any non-federal entity that has never received a negotiated indirect cost rate, (except a governmental department or agency unit that receives more than $35 million in direct federal funding) may elect to charge a de minimis rate of 10% of modified total direct costs (MTDC) which may be used indefinitely. If chosen, this methodology once elected must be used consistently for all federal awards until such time as a non-federal entity chooses to negotiate for a rate, which the non-federal entity may apply to do at any time.

vi. Staffing Plan and Personnel Requirements

You must present a staffing plan and provide a justification for the plan that includes education and experience qualifications and rationale for the amount of time being requested for each staff position. Position descriptions that include the roles, responsibilities, and qualifications of proposed project staff must be included in the Attachment *specified in the FOA*. When applicable, biographical sketches should include training, language fluency and experience working with the cultural and linguistically diverse populations that are served by their programs. They should follow the format described in the FOA and be uploaded as directed in the FOA.

vii. Assurances

Complete Application Form SF-424B Assurances – Non-Construction Programs.

If research involving human subjects is anticipated, you must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in the Code of Federal Regulations, Title 45 – Public Welfare, Part 46 – Protection of Human Subjects (45 CFR part 46), available online at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

NOTE: Please see the Appendix of this *SF-424 R&R Two-Tier Application Guide* for supplemental instructions for preparing the human subjects section of the research plan.

If research involving human subjects is anticipated, you must hold a Federal Wide Assurance (FWA) of compliance from the Office of Human Research Protections (OHRP) prior to award. You must provide your Human Subject Assurance Number (from the FWA) in the application; if you do not have an assurance, you must indicate in the application that you will obtain one from OHRP prior to award.

viii. Certifications

The signature of the AOR on the application serves as the required certification of compliance for the applicant organization for the following:

Lobbying

1) No federal appropriated funds have been paid or will be paid, by or on behalf of the applicant, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any federal contract, the making of any federal grant, the making of any federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any federal contract, grant, loan, or cooperative agreement.

2) If any funds other than federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this federal contract, grant, loan, or cooperative agreement, the applicant must complete and submit Standard Form-LLL, "Disclosure of Lobbying Activities," in accordance with its instructions.

3) Recipients of HRSA awards shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly. This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Federal Debt

Any organization or individual that is indebted to the United States, and has a judgment lien filed against it for a debt to the United States, is ineligible to receive a federal grant. By signing the SF-424 R&R, the applicant is certifying that they are not delinquent on federal debt in accordance with OMB Circular A-129. (Examples of relevant debt include delinquent payroll or other taxes, audit disallowances, guaranteed and direct student loans, benefits that were overpaid, etc.). If an applicant is delinquent on federal debt, they should attach an explanation that includes proof that satisfactory arrangements have been made with the Agency to which the debt is owed. This explanation should be uploaded as an Attachment.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

By submitting this proposal, the prospective recipient is providing the certification set out below:

A. This certification in this clause is a material representation of fact. If it is later determined that the prospective recipient knowingly submitted an erroneous certification, in addition to other remedies available to the Federal Government, the Department may pursue available remedies, including but not limited to, suspension and/or debarment.
B. The prospective recipient shall provide immediate written notice to HRSA if at any time the recipient learns that its certification was erroneous when submitted, or had become erroneous due to changed circumstances.
C. The terms covered transaction, debarred, suspended, ineligible, lower tier covered transaction, participant, person, primary covered transaction, principal, proposal, and voluntarily excluded, as used in this certification, are defined in 2 CFR part 180, as supplemented by 2 CFR part 376.
D. The prospective recipient agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is proposed for debarment under 2 CFR part 180 or 48 CFR part 9, subpart 9.4, debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized in writing by HRSA.
E. The prospective recipient further agrees by submitting this proposal that it will include this clause titled ``Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion,'' without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions, and receive a copy of the signed attestation by such lower tier contractor/subawardee.
F. A recipient may rely upon a certification of a prospective recipient in a lower tier covered transaction that neither it nor its principals, are proposed for debarment under 2 CFR part 180 or 48 CFR part 9, subpart 9.4, debarred, suspended, ineligible, or voluntarily excluded from covered transactions, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. HRSA strongly encourages each participant to check the Excluded Parties database in the System for Award Management at https://www.sam.gov.
G. Nothing contained in this certification requires establishment of a system of records in order to provide the certification required by this certification.
H. Except for transactions authorized under paragraph E of this statement, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is proposed for debarment under 2 CFR part 180 or 48 CFR part 9, subpart 9.4, suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the Department may pursue available remedies, including, but not limited to, suspension and/or debarment.

ix. Project Summary/Abstract

Provide a summary of the application. Because the abstract is often distributed to provide information to the public and Congress, the abstract should be clear, accurate, concise, and without reference to other parts of the application. It must include a brief description of the proposed project including the needs to be addressed, the proposed services, and the population group(s) to be served. See the FOA for additional information that may be required in the project abstract.

The project abstract must be single-spaced and limited to one page in length.

Please place the following at the top of the abstract:

- Project Title
- Applicant Organization Name
- Address
- Project Director Name
- Contact Phone Numbers (Voice, Fax)
- E-Mail Address
- Web Site Address, if applicable
- List all grant program funds requested in the application, if applicable
- If requesting a funding preference, priority, or special consideration as outlined in Section V. 2. of the program-specific FOA, please indicate here.

x. Project Narrative

This section provides a comprehensive framework and description of all aspects of the proposed project. It should be succinct, self-explanatory and well organized so that reviewers can understand the proposed project. Please see the FOA for specific narrative instructions.

xi. Attachments

Provide the attachments as specified in the FOA to complete the content of the application. Unless otherwise noted, attachments count toward the application page limit specified in the FOA. **Each attachment must be clearly labeled**.

5.2. Narrative and Attachment Formatting Guidelines

5.2.1. Font

Please use an easily readable font, such as Times Roman, Arial, Courier, or CG Times. The text and table portions of the application must be single-spaced and submitted in not less than a 12-point font. Applications not adhering to 12-point font requirements may be deemed non-responsive and returned. For charts, graphs, footnotes, and budget tables, you may use a different pitch or size font but not less than 10 pitch or size font. It is vital that the charts are legible when scanned or reproduced.

5.2.2. Paper Size and Margins
For duplication and scanning purposes, please ensure that the application can be printed on 8 ½" x 11" white paper. Margins must be at least one inch at the top, bottom, left and right of the paper. Please left-align text.

5.2.3. Names
Include the name of the applicant and 10-digit grant number (if competing continuation or competing supplement) on each page as a footer.

5.2.4. Section Headings
Put all section headings flush left in bold type.

5.2.5. Page Numbering
Do not number the standard OMB-approved forms. Number each attachment page sequentially. Reset the numbering for each attachment. (Treat each attachment/document as a separate section.)

5.2.6. Allowable Attachment or Document Types
Unless otherwise noted in the FOA, please do not submit organizational brochures or other promotional materials, slides, films, clips, etc.

The attachment types listed below are supported in HRSA EHBs. Although Grants.gov allows you to upload other types of attachments, **HRSA only accepts the following types of attachments. Files with unrecognizable extensions may not be accepted or may be corrupted, and will not be considered as part of the application**. When the application is printed by HRSA, documents will print as they are formatted by you. If using Excel or other spreadsheet documents, be aware that reviewers will only see information that is set in the "Print Area" of the document.

File Attachment Types (acceptable by HRSA)
- .DOC/.DOCX - Microsoft Word
- .RTF - Rich Text Format
- .TXT - Text
- .WPD - Word Perfect Document
- .PDF - Adobe Portable Document Format
- .XLS/.XLSX - Microsoft Excel
- .VSD – Microsoft Visio

File Attachment Names
- Please use only the following characters when naming your attachments: A-Z, a-z, 0-9, underscore (_), hyphen (-), space ( ), period, parenthesis (), curly braces {}, square brackets [], ampersand &, tilde ~, exclamation point !, Comma , Semicolon; Apostrophe ', At sign @, Number sign #, Dollar Sign $, Percent Sign

%, Plus sign +, Equal sign =. Limit the file attachment name to under 50 characters.

Your application will be rejected by Grants.gov if you use special characters or attachment names greater than 50 characters.

5.3. Application Content Order (Table of Contents)

HRSA uses an automatic numbering approach to ensure uniformity of all applications when printed for objective review.

HRSA uses a standard package from Grants.gov (SF-424 R&R), which has defined a standard order of forms (see the table which follows for Grants.gov submission, the program-specific FOA for EHBs submission information). The FOA also provides you with explicit instructions where to upload specific Attachments 1 to maximum of 15.

SF-424 R&R Short Form – Table of Contents

Phase 1: Submission through Grants.Gov

- It is mandatory to follow the instructions provided in this section to ensure that the application can be printed efficiently and consistently for review.
- Failure to follow the instructions may make the application non-responsive. Non-responsive applications will not be considered .
- For electronic submissions, you only have to number the electronic attachment pages sequentially, resetting the numbering for each attachment, i.e., start at page 1 for each attachment. Do not attempt to number standard OMB approved form pages.
- For electronic submissions, no Table of Contents is required for the entire application. HRSA will construct an electronic table of contents in the order specified.

Application Section	Form Type	Instruction	HRSA/Program Guidelines
SF-424 R&R Cover Page	Form	Pages 1 & 2 of the R&R face page.	Not counted in the page limit.
Project/Performance Site Location(s)	Form	Supports primary and 29 additional sites in structured form.	Not counted in the page limit.
Additional Performance Site Location(s)	Attachment	Can be uploaded in the SF-424 R&R Performance Site Location(s) form. Single document with all additional site locations.	Counted in the page limit.
SF-424B Assurance for Non-Construction Programs	Form	Assurance for the SF-424 R&R package.	Not counted in the page limit.
Disclosure of Lobbying Activities (SF-LLL)	Form	Supports structured data for lobbying activities.	Not counted in the page limit. Complete if applicable.

- After successful submission of the Application Forms in Grants.gov (Phase 1), and subsequent processing by HRSA, you will be notified by HRSA confirming the successful receipt of your application. This notification is expected within seven business days from the date of submission in Grants.gov.
- If you do not receive notification within seven business days after submission in Grants.gov, contact the HRSA EHBs Contact Center at 877-GO4- HRSA (877-464-4772) or via the web at http://www.hrsa.gov/about/contact/ehbhelp.aspx. Please have your Grants.gov tracking number at hand.

- Your application will not be considered compliant unless you review and submit the required Attachments in HRSA's EHBs (Phase 2) by the appropriate deadline.

Attachment Number	Attachment Description (Program Guidelines)
Attachments 1-15	Please see instructions in the FOA.

After your application has been successfully processed by HRSA you will receive an e-mail directing you organization to the application in the EHBs, where the required supplemental information must be submitted. Understand that for your application, only the forms mentioned in the Table of Contents listed above are submitted through Grants.gov. All supplemental information, will be submitted through the HRSA EHBs. Refer to the program-specific FOA for more detailed information.

Applicants are reminded that failure to include all required documents as part of the application may result in an application being considered as incomplete or non-responsive.

5.4. Application Page Limit

The total size of all uploaded files may not exceed the page limit specified in Section IV. 2 of the FOA when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support required in the FOA. Standard OMB-approved forms included in the application package, an organization's approved Indirect Cost Rate Agreement, and proof of non-profit status are NOT included in the page limit. All other documents will count toward the page limit, unless noted in the FOA. **We strongly urge you to take appropriate measures to ensure the applicationdoes not exceed the specified page limit.**

Applications must be complete, within the specified page limit, and validated under the correct funding opportunity number prior to the deadline to be considered under the announcement.

You must follow the instructions provided in this section. HRSA recommends that you print out all attachments and confirm the number of pages before submission.

- **NOTE:** Applications that exceed the specified limits or are submitted under the wrong announcement number will be deemed non-responsive, will not be considered for award and the applicants will be notified.

5.5. Submission Dates and Times

Notification of Intent to Apply (ONLY if requested in FOA on cover and in Section IV.7.)
You are eligible to apply even if no letter of intent is submitted. The letter should identify your organization and its intent to apply, and briefly describe the proposal to be submitted. Receipt of Letters of Intent will *not* be acknowledged.

This letter should be sent via email by *the date listed in FOA,* to:

HRSA Digital Services Operation (DSO)
Please use HRSA opportunity number as email subject (HRSA-##-###)
HRSADSO@hrsa.gov

Application Due Date
The due date for applications in Grants.gov (Phase 1) is *11:59 P.M. Eastern Time on the date* listed in Section IV.4 Submission Dates and Times in the FOA, unless otherwise noted. The due date to complete all other required information in HRSA's EHBs (Phase 2) is *5:00 P.M. Eastern Time* on the date listed in Section IV.4 Submission Dates and Times in the FOA, unless otherwise noted. Applications completed online are considered formally submitted and meeting the deadline if: (1) the application has been successfully transmitted electronically to the correct FOA number, by the organization's AOR through Grants.gov and it has been validated by Grants.gov on or before the Grants.gov deadline date and time, and (2) the Project Director has entered the HRSA EHBs to review the application, the Authorizing Official (AO) has submitted the additional information for the application, and it has been successfully received in the HRSA EHBs on or before the EHBs deadline and time.

5.6. Correcting Mistakes

HRSA will only accept your first validated electronic submission, under the correct funding opportunity number, in Grants.gov. Applications submitted after the first submission will be marked as duplicates and considered ineligible for review. If you wish to change information submitted in a Grants.gov application, you may do so in the HRSA Electronic Handbooks (HRSA EHBs) application phase.

It is incumbent on you to ensure that the AOR is available to submit the application to HRSA by the published due date. HRSA will not accept submission or re-submission of incomplete, rejected, or otherwise delayed applications after the deadline. Therefore, you are urged to submit your application in advance of the deadline. If an application is rejected by Grants.gov due to errors, it must be corrected and resubmitted to Grants.gov before the deadline date and time. Deadline extensions will not be provided to applicants who do not correct errors and resubmit before the posted deadline.

5.7. Tips for Writing a Strong Application

HRSA has designed a TA webpage to assist you in preparing your application. Resources include help with system registration, finding and applying for funding opportunities, writing strong applications, understanding the review process, and many other topics which you will find relevant. The website can be accessed online at: http://www.hrsa.gov/grants/apply/index.html.

In addition, a concise resource offering tips for writing proposals for HHS grants and cooperative agreements can be accessed online at http://www.hhs.gov/grants/grants/get-ready-for-grants-management/tips-for-preparing-grant-proposals.

5.8. Withdrawing an Application

You may withdraw your application from consideration at any time before an award is issued. Notification of this withdrawal should be sent via email to DGPWaivers@hrsa.gov, with a copy sent to the Program Contact and Grants Management Specialist listed in the FOA.

6. PROCESS OVERVIEW

6.1. Competing Applications (Phases 1 and 2: Submission Through Grants.gov and the EHBs)

Following is the process for submitting a competing application through Grants.gov:

1) HRSA will post all competing FOAs on Grants.gov (http://www.grants.gov).
2) In order to apply for a HRSA grant, you must complete the Grants.gov registration process. See Section 3 for more details.
3) Once the FOA is available, you should search for the announcement in Grants.gov by clicking the SEARCH GRANTS tab (http://www.grants.gov/web/grants/search-grants.html), entering the FOA number (HRSA-##-###) or clicking the APPLICANTS tab under *Apply for Grants* (http://www.grants.gov/web/grants/applicants/apply-for-grants.html).
4) Download the application package and instructions from Grants.gov. The FOA, accessible via the instructions link, contains application instructions and must be downloaded. Make note of the Announcement Number.
5) Save a copy of the application package on your computer, or to a location you choose and complete all the forms based on the instructions provided in the FOA.
6) Submit the application package through Grants.gov (requires registration – see Section 3).
7) Track the status of your submitted application using Track My Application at Grants.gov until you receive email notifications that your application has been received **and** validated by Grants.gov and received by HRSA. Be sure the application was validated under the correct funding opportunity number.
8) Once your application has been validated by Grants.gov, you may track the status of the application within HRSA by using the "Track Your Application" widget, now available on HRSA's website at http://www.hrsa.gov/grants/index.html. The application tracker will let you know where your application is at every stage in the process.

After successful submission of the Application Forms in Grants.gov (Phase 1), and subsequent processing by HRSA, you will be notified by HRSA confirming the successful receipt of your application.

The following is the process for submitting the supplemental information (Phase 2) through the EHBs:

1) Refer to the FOA for specific information. Program-specific forms are submitted through the EHBs.
2) Refer to Section 4 of this Guide for more application submission information.

6.2. Application Processing

HRSA staff review each application for eligibility, responsiveness, completeness, and conformity with the requirements outlined in the relevant FOA, including programmatic, budgetary, and grants management compliance. Applications that pass the initial HRSA eligibility screening will be reviewed and rated by a panel based on the program elements and review criteria presented in Section V. 1. Review Criteria of the relevant FOA.

All incomplete applications, ineligible, or otherwise non-compliant applications, and applications determined to be non-responsive to FOA requirements will not be reviewed. You may withdraw your application from consideration at any time before an award is issued.

For those applications that did not pass the initial screening, applicants will be advised by letter (sent to the individual signing the application on behalf of the organization) that its application will not be held for further consideration or be funded. The decision not to make an award, or to make an award at a particular funding level, is discretionary and is not subject to appeal to any OPDIV or HHS official or board.

6.3. Objective Review Information

The Division of Independent Review is responsible for managing objective reviews within HRSA. The objective review provides advice to the individual responsible for making award decisions. Objective review is essential to ensuring selection of applications that best meet the needs of the program consistent with published evaluation criteria and providing assurance to the public that the evaluation process is impartial and fair. Applications competing for federal funds receive an objective and independent review performed by a committee of experts qualified by training and experience in particular fields or disciplines related to the program being reviewed. In selecting review committee members, other factors in addition to training and experience may be considered to improve the balance of the committee, e.g., geographic distribution. Each reviewer is screened to avoid conflicts of interest and is responsible for providing an objective, unbiased evaluation based on the review criteria presented in Section V. 1. Review Criteria of the FOA.

Applications that pass the initial HRSA eligibility screening will be reviewed and rated by a panel based on the program elements and review criteria presented in the FOA. The review criteria are designed to enable the review panel to assess the quality of a proposed project and determine the likelihood of its success. The criteria are closely related to each other and are considered as a whole in judging the overall quality of an application.

Procedures for assessing the technical merit of applications have been instituted to provide for an objective review of applications and to assist you in understanding the standards against which each application will be judged. Critical indicators have been developed for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation. Review criteria found in the FOAs are outlined with specific detail and scoring points.

Funding factors may be applied during the objective review process or in the selection process. Funding factors are addressed in the FOA, which will specify if you must make an affirmative request to be considered for a funding factor, what information is needed to demonstrate eligibility for the funding factor, and whether objective reviewers determine if you've met the funding factor. The announcement provides a detailed explanation of preferences, priorities, or special considerations with an explicit indication of their effect (e.g., whether they result in additional points being assigned). It is HRSA policy that funding preferences, priorities, and special considerations must be published in the FOA.

You will receive written notification of the outcome of the objective review process, including a summary of the expert committee's assessment of the application's strengths and weaknesses, and whether the application was selected for funding.

6.4. Award Notification

The Notice of Award (NoA) is the legal document issued to the recipient that indicates an award has been made and that funds may be requested from HRSA. Until an awarding office has issued an NoA for the initial budget period, any costs incurred by the applicant for the project are incurred at its own risk. HRSA may reimburse pre-award costs only to the extent that they would otherwise be allowable. The NoA sets forth the amount of funds granted, the terms and conditions of the award, the effective date of the award, the budget period for which initial support will be given, the non-federal share to be provided (if applicable), and the total project period for which support is contemplated. Signed by the Grants Management Officer (GMO), it is sent to the applicant's Authorized Organization Representative (AOR), and reflects the only authorizing document. Any other correspondence announcing that an application has been selected for award is not an authorization to begin performance. Generally, it will be sent prior to the start date of the award as listed in Section V.4 of the FOA.

A revised NoA may be issued during a budget period to effect an action resulting in a change in the period or amount of support or other change in the terms and conditions of award. An awarding office generally will not issue a revised NoA to reflect a recipient's post-award rebudgeting. Applicants who are selected for funding may be required to respond in a satisfactory manner to conditions placed on their award document before funding can proceed. Letters of notification do not provide authorization to begin performance.

Unsuccessful applicants will receive notification from HRSA's Division of Grants Management Operations.

7. REPORTING REQUIREMENTS

Successful applicants generally must comply with the following standard reporting and review activities, unless otherwise noted in the FOA or NoA. Some programs require program-specific reporting, so please see Section VI. 3. Reporting in the FOA:

a. Audit Requirements

Comply with audit requirements of 45 CFR 75, Subpart F. Information on audits can be found on the Internet at http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4d52364ec83fab994c665943dadf9cf7&ty=HTML&h=L&r=PART&n=pt45.1.75#sp45.1.75.f.

b. Payment Management Requirements

If applicable, the awardee must submit a quarterly electronic Federal Financial Report (FFR) Cash Transaction Report via the Payment Management System (PMS). The report identifies cash expenditures against the authorized funds for the grant or cooperative agreement. The FFR Cash Transaction Reports must be filed within 30 days of the end of each calendar quarter. Failure to submit the report may result in the inability to access award funds. Go to http://www.dpm.psc.gov for additional information.

c. Status Reports

1) **Federal Financial Report**. The Federal Financial Report (SF-425) is required according to the following schedule: http://www.hrsa.gov/grants/manage/technicalassistance/federalfinancialreport/ffrschedule.pdf. The report is an accounting of expenditures under the project that year. Financial reports must be submitted electronically through HRSA EHBs. More specific information will be included in the NoA.

2) **Progress Report**(s). The awardee must submit a progress report to HRSA on a quarterly, semi-annual, or annual basis (as specified in the FOA). For multi-year awards: Submission and HRSA approval of grantee Progress Report(s) triggers the budget period renewal and release of subsequent year funds. This report has two parts. The first part demonstrates grantee progress on program-specific goals. The second part collects core performance measurement data including performance measurement data to measure the progress and impact of the project. Further information will be provided in the NoA.

3) **Final Report.** A final report is due within 90 days after the project period ends. The final report collects information relevant to program-specific goals and progress on strategies; core performance measurement data; impact of the overall project; the degree to which the grantee achieved the mission, goal and strategies outlined in the program; grantee objectives and accomplishments; barriers encountered; and responses to summary questions regarding the grantee's overall experiences during the entire project period. The final report must be submitted online by awardees in the HRSA EHBs system at https://grants.hrsa.gov/grantee.

4) **Tangible Personal Property Report.** If applicable, the awardee must submit the Tangible Personal Property Report (SF-428) and any related forms. The report must be submitted within 90 days after the project period ends. Awardees are required to report all federally-owned property and acquired equipment with an acquisition cost of $5,000 or more per unit. Tangible personal property means property of any kind, except real property, that has physical existence. It includes equipment and supplies. Property may be provided by HRSA or acquired by the recipient with award funds. Federally-owned property consists of items that were furnished by the Federal Government. Tangible personal property reports must be submitted electronically through HRSA EHBs. More specific information will be included in the NoA.

5) **Any other required reports and/or products specified in the FOA**.

d. Transparency Act Reporting Requirements

New awards ("Type 1") issued are subject to the reporting requirements of the Federal Funding Accountability and Transparency Act (FFATA) of 2006 (P. L. 109–282), as amended by section 6202 of P.L. 110–252, and implemented by 2 CFR part 170. IMPORTANT: The reporting requirements apply for the duration of the project period and so include all subsequent award actions to aforementioned HRSA grants and cooperative agreement awards (e.g., Type 2 (competing continuation), Type 5 (non-competing continuation), etc.). Grant and cooperative agreement recipients must report information for each first-tier subaward of $25,000 or more in federal funds and executive total compensation for the recipient's and subrecipient's five most highly compensated executives as outlined in Appendix A to 2 CFR part 170 (FFATA details are available online at http://www.hrsa.gov/grants/ffata.html).

8. AGENCY CONTACTS

8.1. Working with HRSA Program and Grants Management Staff

For assistance with overall program-related questions, contact the PC listed in Section VII. Agency Contacts of the FOA. For additional information regarding business, administrative, or fiscal issues, contact the GMS listed in Section VII. Agency Contacts of the FOA. The PC and the GMS work as a team in many award-related activities.

Please contact Grants.gov Customer Support for technical questions related to Grants.gov.

8.2. Grants.gov Customer Support

Direct all questions regarding Grants.gov to the Grants.gov Call Center at: 1-800-518-4726 (International callers, please dial 606-545-5035) or via email at support@grants.gov. Call Center hours of operation are 24 hours a day, 7 days a week, excluding federal holidays. Please be sure to obtain a case number every time you call so that your issue can be tracked.

For additional support with the Grants.gov Web site, visit http://www.grants.gov/web/grants/support.html. You can also visit the Grants.gov Self Service Knowledge Base for answers to commonly asked questions (https://grants-portal.psc.gov/Welcome.aspx).

9. FAQS AND OTHER INFORMATION

9.1. Software FAQs

9.1.1. What are the software requirements for using Grants.gov?

You will need to download Adobe Reader. For information on Adobe Reader, go to http://www.grants.gov/web/grants/applicants/adobe-software-compatibility.html.

9.1.2. Adobe Reader

The Adobe Reader screen toolbar is shown in **Figure 1** below.

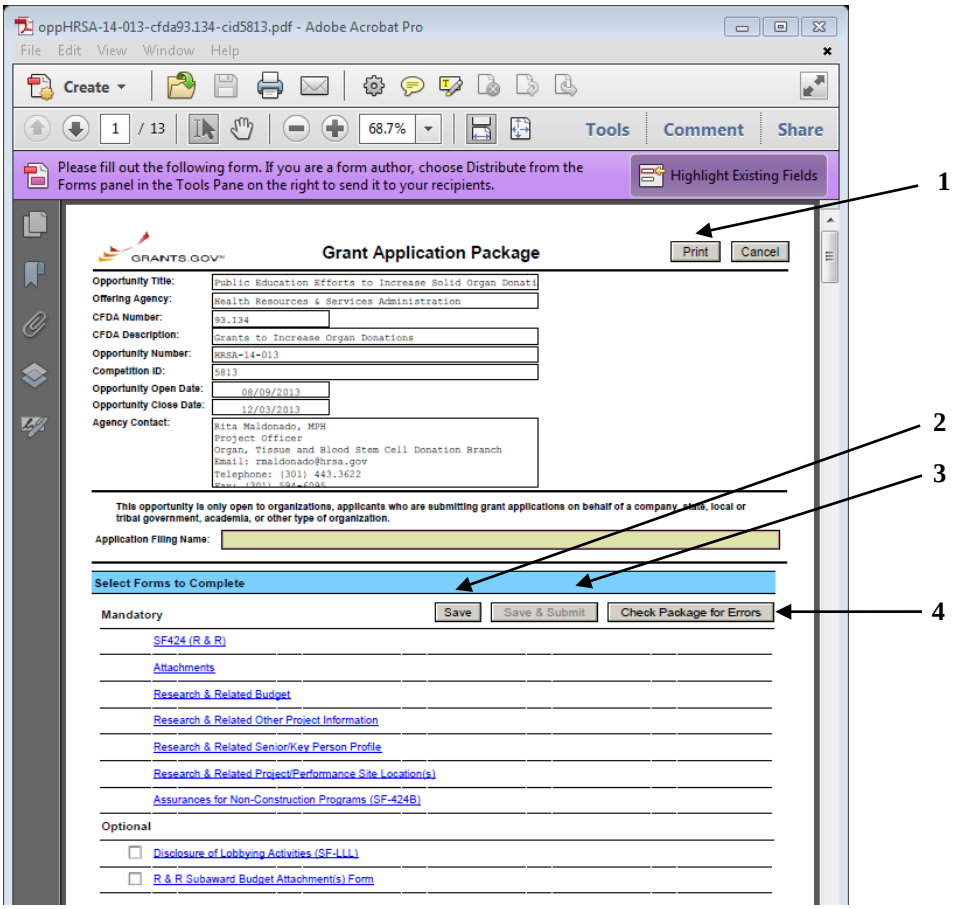

Figure 1: The Adobe Reader Screen Toolbar

1. Print – Click to print the application package.
2. Save – Click to save the application package to your local computer.
3. Save & Submit – Click to submit the application package to Grants.gov. (The **Save & Submit** button on the application package cover page will only become active

after you have completed all required forms, attached all required documents, saved your application package, and your package is free from errors.)

4. Check Package for Errors – Click prior to submitting the application package to ensure there are no errors.

Open and complete all of the documents listed under **Mandatory Documents**, as well as the relevant documents under **Optional Documents**. Refer to **Figure** 2 below.

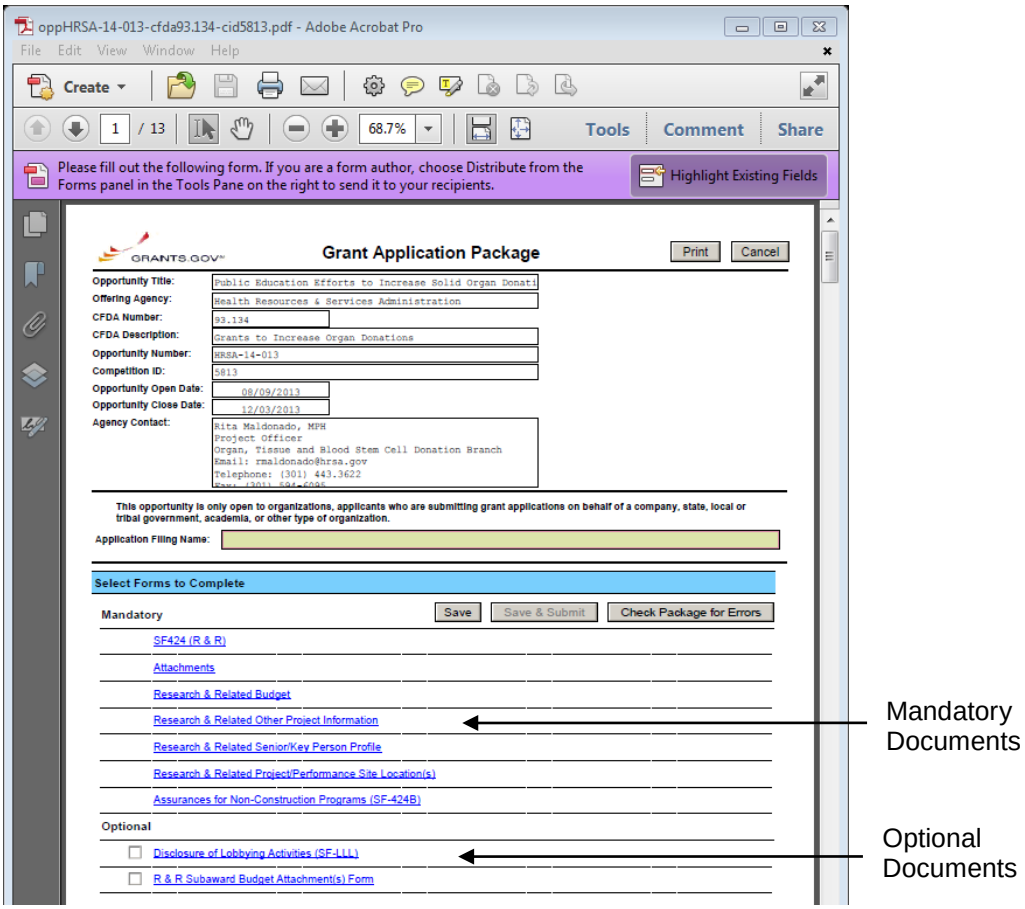

Figure 2: Working with Mandatory Documents (Adobe Reader)

1. The documents listed under Mandatory Documents and Optional Documents may be predefined forms, such as SF-424 (R&R), or documents that need to be attached, such as a staffing plan and job descriptions for key personnel. Mandatory Documents are required for this application. Optional Documents can be used to provide additional support for this application or may be required for specific types of award activity. Reference the FOA for more information regarding Optional Documents.

2. To open a form, click on the form name. It will jump to the first page of the form. For Optional forms, tick first the box on the left of the form name.

3. To remove an optional form, unselect the box on the left of the form name.

4. When you open a required form, the fields which must be completed are noted by an asterisk and highlighted in yellow with a red border. Optional fields and completed fields are displayed in white. If you enter invalid or incomplete information in a field, you will receive an error message.

5. To exit a form within the application, select the **Close Form** button at the top of the form you are filling out. Then to save your work, select the **Save** button (on the cover page) to save your entire application.

Note that the buttons are attached to the top of the page and move with the page. Click on the *Close Form* button to save and close the form. Refer to **Figure 3** below.

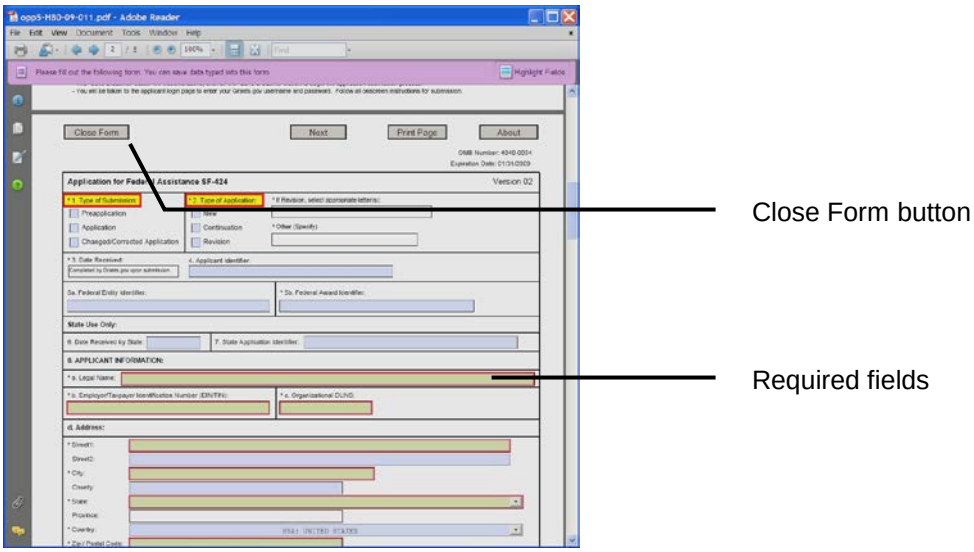

Figure 3: An Open Form in Adobe Reader

Special Note: Working with Earlier Versions of Adobe Reader
It is highly recommended that you remove all earlier versions of Adobe Reader prior to installing the latest version of Adobe Reader. Do this by using *Add or Remove Programs* from the Control Panel in Windows.

If you need to keep older versions of Adobe Reader on your computer, you should be aware that the program will unsuccessfully attempt to open application packages with the earlier, incompatible version. Use the following workaround to avoid this problem.

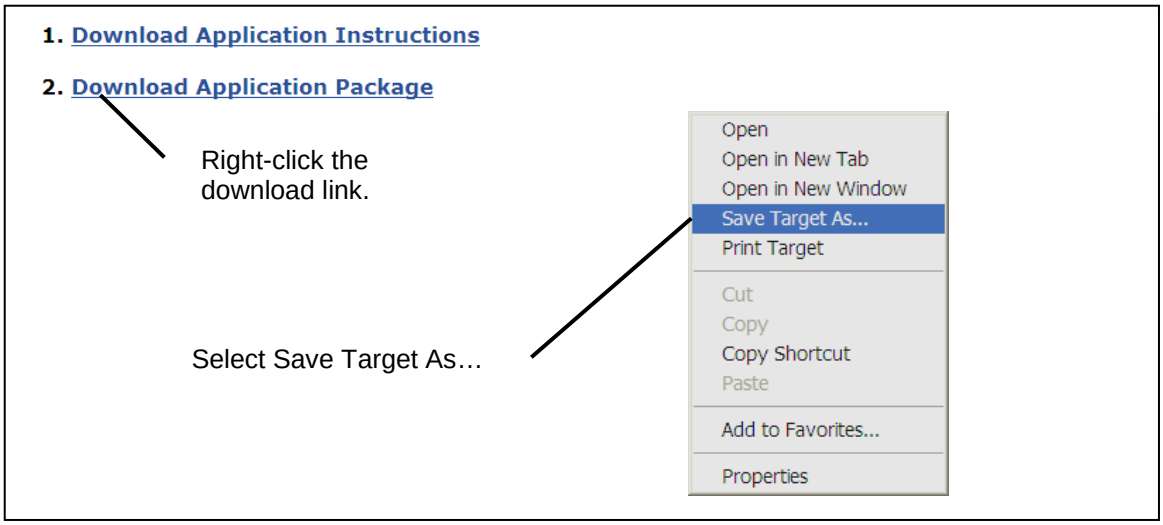

Figure 4: Downloading from Grants.gov

1. From the Grants.gov download page, right-click on the *Download Application Package* link and select **Save Target As**… from the menu.
2. Save the target on your computer (preferably to the Desktop) as an Adobe Acrobat Document.

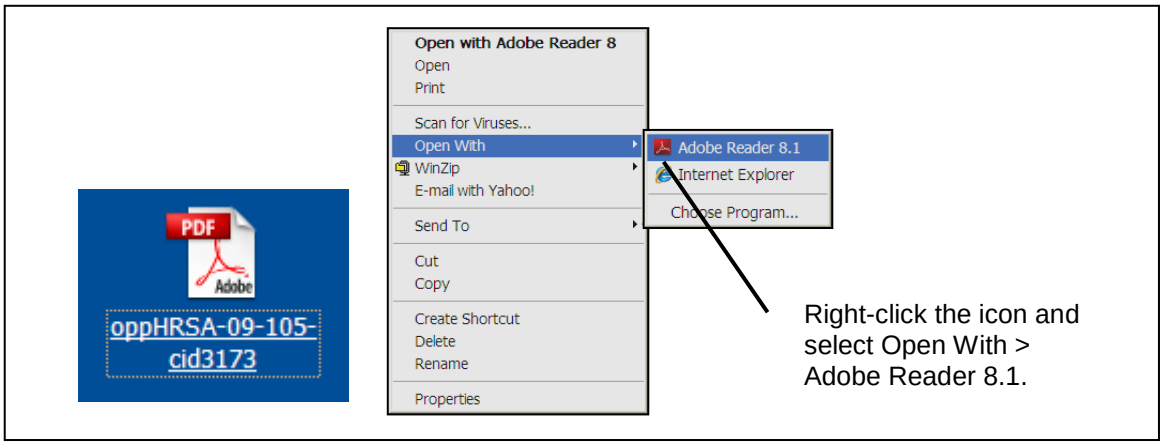

Figure 5: Selecting Open with Adobe Reader

3. Right-click the icon.
4. Select *Open With* > *Adobe Reader 8.1* from the menu.

9.1.3. Can I download Adobe Reader onto my computer?

There are software applications that allow you to successfully navigate the Grants.gov pages and complete your application. These applications can be found at http://www.grants.gov/web/grants/applicants/adobe-software-compatibility.html. However, depending on your organization's computer network and security protocols you may **not** have the necessary permissions to download software onto your workstation. Contact your IT department or system administrator to download the software for you or give you access to this function.

9.1.4. Is Grants.gov Macintosh (Mac) compatible?

Yes, visit http://www.grants.gov/web/grants/support/technical-support/recommended-software.html.

9.2. Application Receipt FAQs

9.2.1. When do I need to submit my application?

Applications must be submitted to Grants.gov (Phase 1) by 11:59 p.m. Eastern Time on the due date unless otherwise specified in the FOA. You should refer to the FOA for exact submission dates and times. An application for HRSA funding must be both received **and** validated by Grants.gov by the application deadline.

After successful submission in Grants.gov (Phase 1) and subsequent processing by HRSA, you will be notified by HRSA confirming the successful receipt of your application and the requirements for the Project Director and Authorizing Official (AO) to review and submit additional information in the HRSA's EHBs (Phase 2). Your application will not be considered compliant and complete unless you review and submit the additional information in HRSA's EHBs by the due date. Both deadlines must be met to be considered in the competition.

9.2.2. What is the receipt date (the date the application is electronically received by Grants.gov or the date the data is received by HRSA)?

The submission/receipt date is the date the application is electronically received and validated by Grants.gov. An application for HRSA funding must be both received **and** validated under the correct funding opportunity number by Grants.gov by the application deadline. Please allow sufficient time to have the application validated, which can take up to 48 hours.

For applications that require verification in HRSA EHBs (refer to the FOA), the submission/receipt date will be the date the application is submitted by your organization's Authorizing Official (AO) in HRSA EHBs. The applicant will receive an "Application Successfully Transmitted to HRSA" message in EHBs upon successful final application submission in HRSA EHBs.

9.2.3 Once my application is submitted, how can I track my application and what emails can I expect from Grants.gov and HRSA?

You can check the status of your application(s) any time after submission by logging into Grants.gov and clicking on the *Track My Application* link. This link will also be included in the confirmation email that you receive from Grants.gov.

When you submit your competing application in Grants.gov, it is first received and then validated by Grants.gov. Typically, this takes a few hours but it may take up to 48 hours during peak volumes. You will receive four emails from Grants.gov.

The first will confirm receipt of your application by the Grants.gov system ("Received"). The second will indicate that the application has either been successfully validated ("Validated") by the system prior to transmission to the grantor agency or has been rejected due to errors ("Rejected with Errors"). An application for HRSA funding must be both received **and** validated under the correct funding opportunity number by Grants.gov by the application deadline.

Subsequently, the application will be downloaded by HRSA upon successful validation of your application by Grants.gov. The status of the application will then change to "Received by Agency" after successful validation and you will receive a third email from Grants.gov.

HRSA will process the application to ensure that it has been submitted for the correct funding announcement number, along with the correct grant number (if applicable) and grantee/applicant organization. This may take up to three business days. HRSA will assign a unique tracking number to your application which will be posted to Grants.gov. The status of your application will then be changed to "Agency Tracking Number Assigned" and you will receive a fourth email from Grants.gov.

- **NOTE:** Refer to FAQ 9.2.5 below for a summary of emails.

9.2.4. If a resubmission is required due to technological problems encountered using the Grants.gov system and the closing date has passed, what should I do?

You must **contact the Director of the Division of Grants Policy at HRSA**, within five calendar days from the closing date, via email at DGPWaivers@hrsa.gov and provide a detailed explanation. Your email must include the HRSA Announcement Number, the name, address, and telephone number of the Organization, the organization's DUNS number, and the Name and telephone number of the Project Director, as well as the Grants.gov Tracking Number (GRANTXXXXXXXX) assigned to your submission, along with a copy of the "Rejected with Errors" notification you received from Grants.gov. Extensions for competitive funding opportunities are only granted in the rare event of a natural disaster or validated technical system problem on the side of the Government that prevented a timely application submission. An application for HRSA funding must

be both received **and** validated under the correct funding opportunity number by the application deadline.

9.2.5 Can you summarize the emails received from Grants.gov and identify who will receive the emails?

Submission Type	Subject	Timeframe	Sent By	Recipient
Competing Application	"Submission Receipt"	Within 48 hours	Grants.gov	AOR
	"Submission Validation Receipt" OR "Rejected with Errors"	Within 48 hours	Grants.gov	AOR
	"Grantor Agency Retrieval Receipt"	Within hours of second email	Grants.gov	AOR
	"Agency Tracking Number Assignment"	Within three business days	Grants.gov	AOR
Competing Application (with verification in HRSA EHBs)	"Submission Receipt"	Within 48 hours	Grants.gov	AOR
	"Submission Validation Receipt" OR "Rejected with Errors"	Within 48 hours	Grants.gov	AOR
	"Grantor Agency Retrieval Receipt"	Within hours of second email	Grants.gov	AOR
	"Agency Tracking Number Assignment"	Within three business days	Grants.gov	AOR
	"Application Ready for Verification"	Within three business days	HRSA	AO, BO, SPOC, PD

9.3. Application Submission FAQ

9.3.1 How can I make sure that my electronic application is presented in the correct order for objective review?

Follow the instructions provided in Section 5 to ensure that your application is presented in the correct order and is compliant with all the requirements.

9.4. Grants.gov FAQs

For a list of frequently asked questions and answers maintained by Grants.gov, please visit http://www.grants.gov/web/grants/applicants/applicant-faqs.html.

Grants.gov offers several tools and numerous user guides to assist applicants that are interested in applying for grant funds. To view the many applicant resources available through Grants.gov please visit http://www.grants.gov/web/grants/applicants/applicant-tools-and-tips.html.

9.5. Application Completeness Checklist

- ❑ Have I read the FOA and this *SF-424 R&R Two-Tier Application Guide* thoroughly?
- ❑ Is my organization eligible to apply for this announcement?
- ❑ Am I applying to the correct funding opportunity number?
- ❑ Is my proposed project responsive to the stated goals and objectives of the program as specified in the FOA?
- ❑ Have I ensured my application does not exceed the ceiling amount specified in Section III of the FOA?
- ❑ Have I completed all forms and attachments as requested in Section IV of the FOA and this Guide?
- ❑ Have I taken the appropriate measures to ensure my application does not exceed the page limit specified in the FOA?
- ❑ Will I apply at least three days prior to the deadline to accommodate any unforeseen circumstances?
- ❑ Have I received confirmation emails from Grants.gov noting validation of successful submission?

9.6. Program-Specific Resources and Technical Assistance

For additional information/resources, refer to Section VIII. Other Information in the FOA. This section may include TA calls (if scheduled), related programs, useful website addresses, etc.

10. TECHNICAL ASSISTANCE RESOURCES

HRSA has developed the How to Apply for a Grant TA webpage at http://www.hrsa.gov/grants/apply. This is a one-stop shop for potential applicants on how to apply for HRSA funding. You will find valuable information on how to apply for HRSA awards, including webcasts, videos, and other technical assistance guidance.

APPENDIX: Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan and Human Subjects Research Policy

1. Introduction

A Protection of Human Subjects section of the Research Plan is required for all applications proposing human subjects research submitted using the SF-424 R&R instructions and forms. The information provided in the section on Protection of Human Subjects should be consistent with the information provided on the face page of the application.

To assist in preparing the section on Protection of Human Subjects, six possible scenarios are provided in Section 2 below. All research projects will fall into one of these six scenarios. Determine which scenario the proposed research falls into, then use the specific instructions applicable to that scenario in Section 3 of this document. Where appropriate, Section 3 also provides instructions on addressing the Inclusion of Sex/Gender and Racial/Ethnic Groups, the Inclusion Enrollment Report(s), and the Inclusion of Children. See the Glossary for definitions related to human subjects research. Section 5 includes descriptions of and links to the HHS Human Subjects Protections regulations that apply to clinical research.

For all scenarios, you must provide sufficient information to allow reviews to determine if the designation of human subjects involvement is appropriate. The proposed research must meet all the requirements of applicable HHS policies for the protection of human subjects from research risks, data and safety monitoring (when applicable), and for the inclusion of sex/gender and racial/ethnic groups, and children and reporting of enrollment data for subjects in clinical research (see the Glossary for definition).

Do not use the human subjects section to circumvent the page limit of the Research Strategy.

While this information is written primarily for competing applications, guidance here may also be applicable to interim progress reports.

2. Scenarios

Scenario A. No Human Subjects Research
If no human subjects research is proposed in the application, you will have designated "No" in response to Human Subjects Research in Item 1 on the SF-424 RESEARCH & RELATED Other Project Information form. If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your

claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

See the instructions for Scenario A.

Scenario B. Non-Exempt Human Subjects Research
If research involving human subjects that does not meet the exemption categories is anticipated to take place under the award, on the SF-424 RESEARCH & RELATED Other Project Information form you will have designated "Yes" in response to "Are Human Subjects Involved?" and "No" in response to "Is the Project Exempt from Federal regulations?" You must provide a complete Protection of Human Subjects section.

See the instructions for Scenario B.

Scenario C. Exempt Human Subjects Research
If **all** of the proposed human subjects research meets the criteria for one or more of the exemptions from the requirements in the HHS regulations (45 CFR § 46.101(b)) (see the Glossary for a detailed description of the exemptions), on the SF-424 RESEARCH & RELATED Other Project Information form you will have designated "Yes" in response to "Are Human Subjects Involved?", "Yes" to "Is the Project Exempt from Federal regulations?", and marked the appropriate exemption number. "NA" should be entered for the Human Subject Assurance Number since no assurance number is required for exempt research.

If you are not sure whether your proposed research qualifies for an exemption, consult with the Office for Human Research Protections (OHRP), Department of Health and Human Services by accessing their Web site http://www.hhs.gov/ohrp/ for guidance and further information.

Please note: if the proposed research involves only the use of human data or biological specimens, you should first determine whether the research involves human subjects. The exemptions do not apply if the research does not involve human subjects.

See the instructions for Scenario C.

Scenario D. Delayed-Onset Human Subjects Research
If human subjects research is anticipated within the period of the award but plans for involvement of human subjects cannot be described in the application as allowed by the HHS regulations (45 CFR § 46.118), if using the SF-424 RESEARCH & RELATED Other Project Information form you will have designated "Yes" in response to "Are Human Subjects Involved?" and, if applicable, "Yes" to "Is the Project Exempt from Federal regulations?" and marked the appropriate exemption number. Examples of delayed-onset of human subjects research include:

- Human subjects research design is dependent upon the completion of animal or other studies; or
- Human subjects research protocols to be conducted will be determined at a later time after award (often defined by a FOA).

See instructions for Scenario D.

Scenario E. Human Subjects Research Involving a Clinical Trial
If research involving human subjects is anticipated to take place under the award, and you intend to conduct a phase I, II, or III clinical trial during the project period that is characterized to include:

a) Prospective assignment of human subjects;
b) One or more interventions, and;
c) Identification of one or more health-related biomedical or behavioral outcomes

If using the SF-424 RESEARCH & RELATED Other Project Information form, you will have designated **"**Yes**"** in response to "Are Human Subjects Involved?", and "No" to "Is the Project Exempt from Federal regulations?"

See instructions for Scenario E.

3. Instructions for Preparing the Section on Protection of Human Subjects

Scenario A. No Human Subjects Research Proposed

Criteria

Human Subjects Research	No
Exemption Claimed	N/A
Clinical Trial	N/A

Instructions and Required Information

If proposed studies involve the use of human data or biological specimens, provide an explanation of why the proposed studies do not constitute research involving human subjects. In the application narrative (Section H Protection of Human Subjects), include the following statement below the section heading: "No Human Subjects Research is proposed in this application" plus any justification as needed.

For studies involving human data or biological specimens, explanation should include: a description of the source of the data/biospecimens; whether they will be collected specifically for this study or were collected for another purpose; what identifiers will be associated with the human specimens and data and who has access to subject

identities; the role(s) of providers of the data/biological specimens in the proposed research; and the manner by which the privacy of research participants and confidentiality of data will be protected.

Research that does not involve intervention or interaction with living individuals, or identifiable private information, is not human subjects research (see the Glossary). Research involving the use of coded private information or biological specimens may not constitute human subjects research if the conditions of the OHRP Guidance on Research Involving Coded Private Information or Biological Specimens have been met (http://www.hhs.gov/ohrp/policy/cdebiol.html).

Research that only proposes the use of cadaver specimens is not human subjects research because human subjects are defined as "living individuals." The use of cadaver specimens is not regulated by 45 CFR part 46, but may be governed by other federal, state or local laws.

Scenario B. Non-Exempt Human Subjects Research

Criteria

Human Subjects Research	Yes
Exemption Claimed	No
Clinical Trial	No

Instructions and Required Information

Although no specific page limitation applies to this section of the application, be succinct. In the application narrative (Section H Protection of Human Subjects), create a subheading for each required topic.

Follow the instructions that are identified for each of the following topics and provide the required information:

- **Protection of Human Subjects** - Section 4.1 - 4.1.4
- **Inclusion of Sex/Gender and Racial/Ethnic Groups**- Section 4.2
- **Inclusion Enrollment Reports(s)** - refer to FOA for details
- **Inclusion of Children** - Section 4.3

If the research involves more than one protocol or subproject, provide the information identified above for each unique protocol or project.

Scenario C: Human Subjects Research Claiming Exemption 1, 2, 3, 4, 5, or 6

Criteria

Human Subjects Research	Yes
Exemption Claimed	1, 2, 3, 4, 5, or 6
Clinical Trial	No

Instructions and Required Information
Although no specific page limitation applies to this section of the application, be succinct. A detailed description of the exemptions can be found in the Glossary.

Although the research may be exempt from the HHS regulatory requirements, the application must follow the instructions that are identified for each of the following topics and provide the requested information.

In the application narrative provide the required information for each of the following topics below:

- **Protection of Human Subjects** - Include the following statement: "This Human Subjects Research falls under Exemption(s) …" Clearly identify which exemption(s) (1, 2, 3, 4*, 5, or 6) you are claiming and justify why the research meets the criteria for the exemption(s) that you have claimed. This justification should explain how the proposed research meets the criteria for the exemption claimed and should not merely repeat the criteria or definitions themselves.
- **Inclusion of Sex/Gender and Racial/Ethnic Groups*** - Section 4.2
- **Inclusion Enrollment Report** -refer to FOA for details
- **Inclusion of Children** - Section 4.3

*NOTE: If all of the proposed research meets the criteria for Exemption 4, then the requirements for inclusion of sex/gender and racial/ethnic groups, and inclusion of children, do not need to be addressed.

Scenario D: Delayed-Onset Human Subjects Research

Criteria

Human Subjects Research	Yes
Exemption	Yes or No
Clinical Trial	Yes or No

Instructions and Required Information

In rare situations, applications are submitted with the knowledge that human subjects will be involved during the period of support, but plans are so indefinite that it is not possible to describe the involvement of human subjects in the application. The kinds of activities that lack definite plans are often institutional awards where the selection of specific projects is made by the institution after award, research networks or multi-site studies where protocols to be conducted are determined after all sites have been selected, or projects in which the involvement of human subjects depends upon initial work in the award such as completion of instruments, animal studies, or purification of compounds.

In the application narrative (Section H Protection of Human Subjects), create a subheading for each required topic.

Follow the instructions that are identified for each of the following topics and EITHER provide as much of the information that is requested as possible, OR describe why it is not possible to provide the information due to delayed-onset of human subjects research.

- **Protection of Human Subjects** - Section 4.1 - 4.1.4
- **Inclusion of Sex/Gender and Racial/Ethnic Groups** - Section 4.2
- **Inclusion Enrollment Report(s)** - refer to FOA for details
- **Inclusion of Children** - Section 4.3

If the research will include a clinical trial, characterized to include (1) prospective assignment of one or more human subjects; (2) one or more intervention (which can include placebo or other control), and; (3) evaluation of the effects of the intervention on one or more health-related biomedical or behavioral outcomes, also include the following topics.

- **Data and Safety Monitoring Plan** - Section 4.1.5
- **ClinicalTrials.gov Requirements** - Section 4.1.6, if applicable

If an award is made, prior to the involvement of human subjects, the grantee must submit to the HRSA awarding office for prior approval either (1) detailed information as required in the Research Plan, Protection of Human Subjects (addressing risks to the subjects, adequacy of protection against risks, potential benefits of the proposed research, importance of the knowledge to be gained, and data and safety monitoring plan, if applicable), Human Subjects Assurance number, and certification of IRB approval, OR (2) if all of the research meets the criteria for one or more exemptions, identification of which exemption(s) is/are applicable to the research, and a justification for the exemption with sufficient information about the involvement of human subjects to allow a determination that the claimed exemption is appropriate.

Under no circumstance may human subjects be involved in research until approval is granted by the awarding entity, and certification of IRB approval (or justification for exemption) has been accepted by the agency. Inclusion plans and inclusion enrollment report(s) must also be submitted to the agency prior to starting human subjects studies.

Scenario E: Clinical Trial

Criteria

Human Subjects Research	Yes
Exemption	No
Clinical Trial	Yes

Instructions and Required Information

In the application narrative (Section H Protection of Human Subjects), include the following statement below the heading: “This Human Subjects Research meets the definition of a clinical trial.” (See definition of "clinical trial" in the Glossary.) Additionally, create a subheading for each required topic discussed below. Provide the required information for each of the following topics below:

For each clinical trial proposed, follow the instructions that are identified for each of the following topics and provide the required information:

- **Protection of Human Subjects -** Section 4.1 - 4.1.4
- **Data and Safety Monitoring –** Section 4.1.5
- **ClinicalTrials.gov Requirements** - Section 4.1.6, if applicable
- **Inclusion of Sex/Gender and Racial/Ethnic Groups**- Section 4.2
- **Inclusion Enrollment Report(s)** - refer to FOA for details
- **Inclusion of Children** - Section 4.3

If the research involves more than one trial/protocol or subproject, provide the information identified above for each unique protocol or project.

4. Instructions Pertaining to Non-Exempt Human Subjects Research

This information will be placed in your application narrative (Section H Protection of Human Subjects). Although no specific page limitation applies to this section of the application, be succinct. Scientific Review Groups will assess each application as being acceptable or unacceptable with regard to the protection of human subjects. HHS regulations and policies governing human subjects research are described and referenced in Section 5 below. Use subheadings to address the issues listed under items Sections 4.1-4.4 below. If your research includes a clinical trial, include a separate document entitled "Data and Safety Monitoring Plan" and follow the instructions in Section 4.1.5 below. If your research includes a Phase III Clinical Trial, also follow the additional instructions in Section 4.2.1 below.

4.1 Protection of Human Subjects

4.1.1 Risks to Human Subjects

a) ***Human Subjects Involvement, Characteristics, and Design***

- Describe and justify the proposed involvement of human subjects in the work outlined in the Research Strategy section.
- Describe the characteristics of the subject population, including their anticipated number, age range, and health status, if relevant.
- Describe and justify the sampling plan, including retention strategies and the criteria for inclusion or exclusion of any subpopulation.

- If relevant, explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that 'prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers) as well as subjects who become incarcerated after the study begins.
- If relevant to the proposed research, describe procedures for assignment to a study group. As related to human subjects protection, provide details about all planned interventions such as dose, frequency, and administration.
- List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research. Explain how data from the site(s) will be obtained, managed, and protected.

b) Sources of Materials

- Describe the research material obtained from living individuals in the form of specimens, records, or data.
- Describe any data that will be collected from human subjects for the project(s) described in the application.
- Indicate who will have access to individually identifiable private information about human subjects.
- Provide information about how the specimens, records, and/or data will be collected, managed, and protected, as well as whether any individually identifiable private information will be collected specifically for the proposed research project.

c) Potential Risks

- Describe all the potential risks to subjects posed by participation in the research (physical, psychological, financial, legal, or other), and assess their likelihood and seriousness to the human subjects.
- Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of the alternative treatments and procedures, to participants in the proposed research. When alternative treatments or procedures are possible, the rationale for the proposed approach should be clear.

4.1.2 Adequacy of Protection Against Risks

a) Recruitment and Informed Consent

- Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.

- Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. When appropriate, describe how potential adult subjects' capacity to consent will be determined and plans for obtaining consent from a legally authorized representative for adult subjects not able to consent.
- If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver. Informed consent document(s) need not be submitted to HRSA unless requested.

b) Protections Against Risk

- Describe planned procedures for protecting against or minimizing all potential risks identified, including risks to privacy of individuals or confidentiality of data, and assess their likely effectiveness.
- Describe how proposed research involving vulnerable populations meets the additional regulatory requirements described in the HHS regulations, Subparts B, C or D. Refer to HHS regulations, and OHRP guidance:
    - Additional Protections for Pregnant Women, Human Fetuses and Neonates: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb
    - Additional Protections for Prisoners: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc
    - OHRP Subpart C Guidance: http://www.hhs.gov/ohrp/regulations-and-policy/guidance/prisoner-research-ohrp-guidance-2003/
    - Additional Protections for Children: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd
    - OHRP Subpart D Guidance: http://www.hhs.gov/ohrp/policy/index.html#children
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Studies that involve clinical trials (see definition of "clinical trial" in the Glossary) must include a separate attachment describing the plan for data and safety monitoring of the clinical trials and adverse event reporting to the IRB, the Data and Safety Monitoring Board (DSMB) (if one has been established for the trial), HRSA and others, as appropriate, to ensure the safety of subjects (see Section 4.1.5 below).
- Where appropriate, describe plans for handling incidental findings that may be uncovered as a result of the research, such as incidental findings from research imaging, results of screening tests, or misattributed paternity.

NOTE: Test articles (investigational new drugs, devices, or biologics) including test articles that will be used for purposes or administered by routes that have not been approved for general use by the Food and Drug Administration (FDA) must be named. State whether the 30-day interval between submission of applicant certification to the

FDA and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the FDA, and/or the status of requests for an Investigational New Drug (IND) or Investigational Device Exemption (IDE) covering the proposed use of the test article in the Research Plan.

4.1.3 Potential Benefits of the Proposed Research to Human Subjects and Others

- Discuss the potential benefits of the research to research participants and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.
- Please note that financial compensation of subjects should not be presented as a benefit of participation in research.

4.1.4 Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

4.1.5 Data and Safety Monitoring Plan

The PHS Data and Safety Monitoring Policy is described and referenced in Section 5.3.

If the proposed research includes a clinical trial, create a heading in Section H Protection of Human Subjects entitled "Data and Safety Monitoring Plan." Provide a data and safety monitoring plan (DSMP) that is commensurate with the risks of the trial and its size and complexity. You must provide a description of the DSMP that you are proposing to establish for each clinical trial proposed, including:

- The overall framework for safety monitoring and what information will be monitored.
- The frequency of monitoring, including any plans for interim analysis and stopping rules (if applicable).
- The process by which Adverse Events (AEs), including Serious Adverse Events (SAEs) such as deaths, hospitalizations, and life threatening events, and Unanticipated Problems (UPs), will be managed and reported as required to the Institutional Review Board (IRB), the person or group responsible for monitoring, and HRSA.
- The individual(s) or group that will be responsible for trial monitoring and advising the appointing entity. Because the monitoring plan will depend on potential risks, complexity, and the nature of the trial, a number of options for monitoring are possible. These include, but are not limited to, monitoring by a:

- Project Director (PD)/Principal Investigator (PI): While the PD/PI must ensure that the trial is conducted according to the protocol, in some cases (e.g., low risk trials, not blinded), it may be acceptable for the PD/PI to also be responsible for carrying out the DSMP.
- Independent safety monitor/Designated medical monitor: a physician or other expert who is independent of the study.
- Independent Monitoring Committee or Safety Monitoring Committee: A small group of independent investigators and biostatisticians.
- Data and Safety Monitoring Board (DSMB): a formal independent board of experts including investigators and biostatisticians. As noted in Section 5.3, PHS requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials. Although Phase I and Phase II clinical trials may also need DSMBs, smaller clinical trials may not require this oversight format, and alternative monitoring plans may be appropriate.
- If a DSMB is used, please describe the general composition of the Board without naming specific individuals.

4.1.6 ClinicalTrials.gov Requirements

Public Law 110-85 (also known as the FDA Amendments Act (FDAAA) of 2007) mandates registration and results reporting of "applicable clinical trials" in ClinicalTrials.gov. Under the statute these trials generally include: (1) Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation; and (2) Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric postmarket surveillance. Review the statutory definition of applicable clinical trial to identify if registration is required to comply with the law (See PL 110-85, Section 801(a), adding new 42 U.S.C. 282(j)(1)(A)).

PHS encourages registration and results reporting for ALL clinical trials whether or not registration is required under the FDAAA. On January 28, 2015, NCI published a policy requiring the reporting of final trial results in a publicly accessible manner within 12 months of the trial's primary completion date.

When registering clinical trials in the ClinicalTrials.gov Protocol Registration System, if applicable, enter the HRSA Grant Number associated with the trial in the "Secondary ID" field (example: R40MC#####).

Registration is accomplished at the ClinicalTrials.gov Protocol Registration System Information Web site (https://clinicaltrials.gov/). A unique identifier called an NCT number, or ClinicalTrials.gov registry number, will be generated during the registration process. This number should be included in all Progress Reports and publications.

FDAAA requires:

- the registration of applicable clinical trials in ClinicalTrials.gov no later than 21 days after the first subject is enrolled,
- the reporting of summary results information (including adverse events) no later than one year after the completion date for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA, and
- if an "applicable clinical trial" is funded in whole or in part by a HRSA grant or cooperative agreement, grant and progress report forms shall include a certification that the responsible party has made all required submissions to ClinicalTrials.gov.

For competing new and renewal applications that include applicable clinical trials which require registration and results reporting under FDAAA, provide the NCT number/s in the human subjects section of the Research Plan under a section heading entitled ClinicalTrials.gov.

The entity responsible for registering the trial is the "responsible party." The statute defines the responsible party as:

1) the sponsor of the clinical trial (as defined in 21 CFR § 50.3) (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.3), or
2) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee (provided that "the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements" for submitting information under the law) (http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid =f:publ085.110.pdf). See PL 110-85, Section 801(a), (adding new 42 U.S.C. 282(j)(1)(A)(ix)).

For the complete statutory definitions of "responsible party" and "applicable clinical trial," refer to Elaboration of Definitions of Responsible Party and Applicable Clinical Trial.

The signature on the application of the Authorized Organization Representative assures compliance with FDAAA.

4.2 Inclusion of Sex/Gender and Racial Ethnic Groups

In Section I Targeted Enrollment of the application narrative, create a section subheading entitled "Inclusion of Sex/Gender and Racial/Ethnic Groups". Although no specific page limits apply to this section of the application, be succinct. This section

does not take the place of considering relevant biological variables (such as sex) in the research strategy. The PHS Policy on the Inclusion of Sex/Gender and Racial/Ethnic Groups in Clinical Research is described and referenced in Section 5.6.

Scientific Review Groups (ie, the Objective Review Committees at HRSA) will assess each application as being acceptable or unacceptable with regard to the scientifically justified inclusion (or exclusion) based on sex/gender, race, and ethnicity in clinical research (see the Glossary for definition). This section is required for all studies meeting the definition for clinical research, not just clinical trials. It is important to provide a detailed plan of who will be included (and/or excluded) and how the distributions of individuals on the basis of sex/gender, race, and ethnicity are justified in the context of the scientific goals of the application. Simply stating that certain individuals will not be excluded or that individuals of any sex/gender or race/ethnicity are eligible is not sufficient. Details about why the individuals are the appropriate individuals to accomplish the scientific goals of the study should be provided.

In this section, address, at a minimum, the following four points:

1) Describe the planned distribution of subjects by sex/gender, race, and ethnicity for each proposed study.
2) Describe the subject selection criteria and rationale for selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition understudy.
3) Provide a compelling rationale for proposed sample specifically addressing exclusion of any sex/gender, racial, or ethnic group that comprises the population under study.
4) Describe proposed outreach programs for recruiting sex/gender, racial, and ethnic group members as subjects. This is particularly important if difficulty recruiting certain groups is anticipated.

Additional Considerations for justifying inclusion:

There may be reasons why the proposed sample is limited by sex/gender, race, and/or ethnicity. This should be addressed as part of the four points detailed above.

- Inclusion of certain individuals would be inappropriate with respect to their health;
- The research question addressed is only relevant to certain groups or there is a gap in the research area;
- Evidence from prior research strongly demonstrates no difference on the basis of sex/gender, race, and/or ethnicity;
- Sufficient data already exist with regard to the outcome of comparable studies in the excluded group(s)and duplication is not needed in this study;

- A certain group or groups is excluded or severely limited because the purpose of the research constrains the applicant's selection of study subjects (e.g., uniquely valuable stored specimens or existing datasets are limited by sex/gender, race, and/or ethnicity; very small numbers of subjects are involved; or overriding factors dictate selection of subjects, such as matching of transplant recipients, or availability of rare surgical specimens); and/or
- Representation of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens, or data-sets with incomplete sex/gender documentation are used), and this does not compromise the scientific objectives of the research.
- In general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups. This should be considered when developing outreach plans. Establishing collaborations or other arrangements to recruit may be necessary.
- Additional guidance for research utilizing existing datasets or resources:
    - Inclusion must be addressed when conducting clinical research, even if the samples or data have already been collected as part of a different study. Details about the sex/gender, race, and ethnicity composition of the existing dataset/resource should be provided and justified as appropriate to the scientific goals of the proposed study.
    - For the purposes of inclusion policy, an existing dataset may be constructed of different types of data including but not limited to survey data, demographic information, health information, genomic information, etc. Also included would be data to be derived from existing samples of cells, tissues, or other types of materials that may have been previously collected for a different purpose or research question but will now be used to answer a new research question. In general, these will be studies meeting the definition for clinical research with a prospective plan to analyze existing data and/or derive data from an existing resource and where no ongoing or future contact with participants is anticipated.

4.2.1 Additional Instructions and Requirements When Large Clinical Trials Are Proposed

If the proposed research includes a large Clinical Trial (ie, a randomized controlled trial with several hundred or several thousand participants), the section on Inclusion of Sex/Gender and Racial/Ethnic Groups also MUST address plans for how sex/gender, race, and ethnicity will be taken into consideration in the design and valid analysis of the trial. Valid analysis means an unbiased assessment which will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need to have a high statistical power for detecting a stated effect.

Scientific Review Groups (ie, the Objective Review Committees at HRSA) will assess each application as being acceptable or unacceptable with regard to the scientifically justified inclusion plans, including these additional requirements for Phase III clinical trials.

Applicants should address the following issues for ensuring valid analyses:

- Inclusive eligibility criteria – in general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups;
- Allocation of study participants rom different sexes/genders and racial/ethnic groups to the intervention and control groups by an unbiased process such as randomization;
- Unbiased evaluation of the outcome(s) of study participants; and
- Use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects by sex/gender, race, and/or ethnicity, particularly if prior evidence strongly suggests that differences exist.

Applicants also should address whether they plan to test or not test for differences in effect among sex/gender, racial, and/or ethnic groups and why that is or is not appropriate. This may include supporting evidence and/or data derived from animal studies, clinical observations, metabolic studies, genetic studies, pharmacology studies as well as observational, natural history, epidemiology and/or other relevant studies. Additional factors may include planned primary and secondary outcomes and whether there are previous studies that support or negate the likelihood of differences between groups.

The plans must include selection and discussion of one of the following analysis plans:

- Plans to conduct analyses to detect significant differences in intervention effect among sex/gender, racial, and/or ethnic subgroups when prior studies strongly support these significant differences among one or more subgroups, or
- Plans to include and analyze sex/gender, racial, and/or ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender, racial, and ethnic groups is not required as subject selection criteria, but inclusion is encouraged), or
- Plans to conduct valid analyses of the intervention effect in sex/gender, racial, and/or ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect among subgroups.

4.3 Inclusion of Children

Create a subsection entitled “Inclusion of Children” and place it immediately following the subsection on the Inclusion of Sex/Gender and Racial/Ethnic Groups. Although no specific page limits apply to this section of the application, be succinct. The Policy on

Inclusion of Children is referenced and described in Section 5.8 for inclusion in the application narrative section. For the purpose of implementing these guidelines, a *child* is defined as an individual under the age of 18 years.

Scientific Review Groups (ie, the Objective Review Committees at HRSA) will assess each application as being acceptable or unacceptable with regard to the age-appropriate inclusion or exclusion of children in the proposed research project. This section is required for all studies meeting the definition for clinical research, not just clinical trials. It is important to provide a detailed plan of who will be included (and/or excluded) based on age. Details about why the individuals in the given age/age range are the appropriate individuals to accomplish the scientific goals of the study should be provided.

Instructions for this item of the Research Plan, **including addressing the following points**:

- Describe the age(s) or age range of all individuals to be included in the proposed study.
- Specifically discuss whether children under the age of 18 (as a whole or a subset of individuals under 18) will be included or excluded.
- The description of the plan should include a rationale for selecting a specific age range of children.
- The plan also must include a description of the expertise of the investigative team for working with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.
- When children are involved in research, the Additional Protections for Children Involved as Subjects in Research (45 CFR part 46 Subpart D) apply and must be addressed under the Protections Against Risk subheading (4.1.2.b).

Justifications for Exclusion of Children

For the purposes of this policy, individuals under 18 are defined as a child; however, exclusion of any specific age or age range group should be justified in this section. It is expected that children will be included in all clinical research unless one or more of the following exclusionary circumstances apply:

- The research topic to be studied is not relevant to children.
- Laws or regulations bar the inclusion of children in the research.
- The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be needlessly redundant. Documentation of other studies justifying the exclusions should be provided. HRSA program staff can be contacted for guidance on this issue if the information is not readily available.

- A separate, age-specific study in children is warranted and preferable. Examples include:
  - The condition is relatively rare in children, as compared to adults (in that extraordinary effort would be needed to include children, although in rare diseases or disorders where the applicant has made a particular effort to assemble an adult population, the same effort would be expected to assemble a similar child population with the rare condition); or
  - The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
  - Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages or different age-related metabolic processes). While this situation may represent a justification for excluding children in some instances, consideration should be given to taking these differences into account in the study design and expanding the hypotheses tested, or the interventions planned, to allow inclusion of children rather than excluding them.
- Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). Although children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis.
- Study designs are aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children).
- Other special cases can be justified by the investigator and assessed by the review group and HRSA to determine if acceptable.

5. Human Subjects Research Policy

Human Subjects Research Policy includes HHS regulations for the protection of human subjects and the following PHS policies related to human subjects research.

5.1 Protection of Human Subjects

The Department of Health and Human Services (HHS) regulations for the Protection of Human Research Subjects, 45 CFR part 46, provide a systematic means, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the HHS. The regulations stipulate that the awardee organization, whether domestic or foreign, bears responsibility for safeguarding the rights and welfare of human subjects in HHS-supported research activities. The regulations require that all organizations engaged in nonexempt human subjects research supported or conducted by the HHS hold a Federal-wide Assurance (FWA) with the Office for Human Research

Protections (OHRP), and establish appropriate policies and procedures for the protection of human subjects. These regulations are available from OHRP, Department of Health and Human Services, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD; telephone: 1-866-447-4777 (toll-free) or (240) 453-6900; e-mail: ohrp@hhs.gov. In general, OHRP considers organizations that receive direct support from HHS for the conduct of non-exempt human subjects research to be engaged in human subjects research. (For more information on whether an institution is engaged in human subjects research, refer to: http://www.hhs.gov/ohrp/policy/engage08.html). When a research project is conducted by multiple organizations, each organization that is engaged in non-exempt human subjects research must hold an FWA and comply with the regulations at 45 CFR part 46.

Non-exempt research involving human subjects may only be conducted under an HHS award if the engaged organization(s) is operating in accord with an approved FWA and provides verification that an Institutional Review Board (IRB) that is registered with OHRP has reviewed and approved the proposed activity in accordance with the HHS regulations. Foreign applicant organizations must also comply with the provisions of the regulations.

Under HHS regulations to protect human subjects, certain research activities are exempt. With the exception of research projects that meet the criteria for Exemption 4, studies that are exempt from the human subjects regulatory requirements must still address the inclusion of sex/gender and racial/ethnic groups, and children in the study design.

Regulations of the Food and Drug Administration (21 CFR part 50, 21 CFR part 56) generally apply to biomedical research involving an unapproved drug, device or biologic and may apply to certain studies of approved products. Additional information on FDA regulations is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm. If work falls under FDA's regulatory requirements, the grantee must follow both HHS and FDA human subject protection regulations.

Federal requirements to protect human subjects may apply to research on human specimens (such as cells, blood, and urine), residual diagnostic specimens, and medical information. Research involving existing data, documents, records, pathological specimens, diagnostic specimens, or tissues that are individually identifiable is considered “research involving human subjects.” Research involving the use of coded private information or biological specimens may not constitute human subjects research. Refer to the OHRP Guidance on Research Involving Coded Private Information or Biological Specimens to clarify when such research is or is not research involving human subjects: http://www.hhs.gov/ohrp/policy/cdebiol.html.

The HHS regulations require HRSA to evaluate all applications and proposals involving human subjects (45 CFR § 46.120). This independent evaluation is conducted through

the objective review system and HRSA staff review, and, as required, will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. On the basis of this evaluation, HRSA may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

5.1.1 Research Involving the Use of Newborn Blood Spots

Federally funded research using newborn dried blood spots collected on or after March 18, 2015, is considered to be non-exempt human subjects research, and therefore, must follow the HHS protection of human subjects regulations at 45 CFR part 46.

Grant applications submitted to HRSA that will use such materials in research should be designated as non-exempt human subjects research and include a complete Protection of Human Subjects section per these instructions including plans for inclusion on the basis of sex/gender, race, ethnicity, and age.

Such applications that are funded by HRSA must comply with all the relevant federal regulatory and policy requirements for human subjects research including the requirement that the awardee institution (and all engaged institutions) have a Federal-wide Assurance (FWA) from OHRP and certification of IRB approval of the proposed research.

Parental permission must have been obtained in order to use newborn dried blood spots collected on or after March 18, 2015, in HRSA-funded research. Waiver of parental permission for such research is not permitted under this legislation.

Section 12 of the Newborn Screening Saves Lives Reauthorization Act of 2014 applies to use of newborn dried blood spots in HHS-funded research. Research funded solely by state or private entities does not constitute “federally funded research” and is not subject to Section 12 of the new law. Non-identifiable newborn dried blood spots collected prior to March 18, 2015, may continue to be used in NIH-funded research without parental permission, and this activity would continue to be considered research that does not involve human subjects under the current human subjects regulations.

5.2 Vulnerable Populations

Investigators who conduct research involving pregnant women, human fetuses and neonates, prisoners (including subjects who become prisoners after the research has started), or children, must follow the provisions of the regulations in Subparts B, C, or D of 45 CFR part 46, respectively. The subparts describe the additional protections required for conducting research involving these populations. Relevant information may be obtained at the OHRP Web site (http://www.hhs.gov/ohrp/regulations-and-policy/index.html).

Exemptions 1-6 (see Exemptions in the Glossary) do **not** apply to research involving prisoners or subjects who become prisoners (see Subpart C). Although Exemptions 1 and 3-6 apply to research involving children (see Subpart D), Exemption 2 can only be used for research involving educational testing or observations of public behavior when the investigator(s) do(es) not participate in the activities being observed.

5.3 Data and Safety Monitoring Plans for Clinical Trials

For each proposed clinical trial (See definition of "clinical trial" in the Glossary), a data and safety monitoring plan is required that describes oversight and monitoring to ensure the safety of participants and the validity and integrity of the data. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial. Prior to the accrual of human subjects, a detailed data and safety monitoring plan must be submitted to the applicant's IRB and to the funding entity for approval. Adverse Events must be reported to the IRB, HRSA, and other appropriate offices or agencies. This policy requirement is in addition to any monitoring requirements imposed by 45 CFR part 46.

The establishment of a Data and Safety Monitoring Board (DSMB) is specifically required for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials. A DSMB also may be appropriate for clinical trials if the studies are blinded (masked), employ high-risk interventions, or involve vulnerable populations.

Summary reports of adverse events must be provided to HRSA, individual IRBs and to the DSMB (if one has been established for the trial) or other monitoring entity in order for them to address reports related to the site for which they have responsibility. Grantees should address questions on this subject to the HRSA Program Official.

5.4 IRB Approval

HRSA does not require certification of IRB approval of the proposed research prior to objective review of an application

Following HRSA objective review, applicants and their institutions will be notified of the need for review and approval of the proposed research by an IRB that is registered with OHRP (if it has not already been approved). See http://www.hhs.gov/ohrp/ to register an IRB. Certification of IRB approval must be sent to the Grants Management Office identified in the notice requesting documentation.

Because HHS human subject regulations at 45 CFR § 46.103(f) require that each application for HHS-supported non-exempt human subject research be reviewed and approved by an IRB (see also http://www.hhs.gov/ohrp/policy/aplrev.html) the date of approval of the application must be submitted to HRSA. However, the IRB must ensure

that any corresponding protocol(s) are consistent with the application, and must maintain documentation of IRB approval of all corresponding protocols, including those reviewed by consortium participants. For multi-site research that is not using a single IRB of record, the primary grantee is expected to collect the certification from each subrecipient.

Awardees involved in multi-site research may agree to rely on a single IRB of record. The IRB of record must have an assurance with OHRP. Following OHRP guidance, HRSA expects that such reliance arrangements will be documented through the signing of an IRB Authorization Agreement.

Any modifications to the Research Plan in the application, required by either HRSA or by the IRB, must be submitted with follow-up certification of IRB approval to HRSA before any research activities involving human subjects are initiated. It is the responsibility of the PD/PI and the applicant organization to submit the follow-up documentation.

IRB approval must be dated within the last year to be valid. If more than a year will have elapsed between the initial IRB review date and the anticipated award date, HRSA shall require re-review by the IRB prior to award.

Continuing IRB review of ongoing human subjects research is also required by 45 CFR § 46.109(e). A progress report for continuation support should not be submitted until certification of annual IRB review has been obtained. The awardee institution must track and document IRB approval for all components of an award that involve human subjects. Progress reports should report the most recent IRB approval date for any component which the IRB has approved.

5.5 Required Education in the Protection of Human Research Participants

HRSA requires education on the protection of human research participants for all individuals identified in applications as senior/key personnel who will be involved in the design or conduct of human subjects research, before funds are awarded for applications or contract proposals involving human subjects. For information relating to this requirement, see the following notices http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html and http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-061.html, and Frequently Asked Questions at: http://grants.nih.gov/grants/policy/hs_educ_faq.htm. Prior to initiating any research activities involving human subjects, institutions will be required to certify to HRSA that all senior/key personnel involved in the design or conduct of human subjects research have completed this educational requirement. Although HRSA does not endorse specific programs, curricula are available to provide guidance and can be modified to provide training in this area. For information on facilitating education and developing curricula, see http://www.nih.gov/sigs/bioethics. Also, NIH has a free tutorial on human

subjects protection that can be used to meet this educational requirement: see http://grants.nih.gov/grants/policy/hs/training.htm.

5.6 Policy on the Inclusion of Sex/Gender and Racial/Ethnic Groups in Clinical Research

PHS policy requires that all PHS-supported biomedical and behavioral research projects involving clinical research include diverse sex/gender and racial/ethnic minority populations unless a clear and compelling rationale and justification establishes to the satisfaction of the funding agency that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances must be designated by the Associate Administrator or Office Director, upon the recommendation of a HRSA program office based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy applies to research subjects of all ages.

Representation of diverse racial/ethnic minority populations, as well as sex/gender, must be addressed in developing a research design appropriate to the scientific objectives of the study. The Research Plan should describe the composition of the proposed study population in terms of sex/gender, race, and ethnicity, and provide a rationale for selection of subjects. It is important to justify the proposed sample on the basis of sex/gender, race, and ethnicity in the context of the scientific goals of the proposed study(s) with discussion of the demographics of the population under study and/or who is at risk for the disease/condition. Such a plan should contain a description of the proposed outreach programs for recruiting women and racial/ethnic minorities as participants.

In addition, as detailed in Section 4.2.1 of these instructions, when conducting a clinical trial, there are additional requirements and considerations related to valid analysis to explore differences on the basis of sex/gender, race, and ethnicity.

5.7 PHS Policy on Reporting Race and Ethnicity Data for Subjects in Clinical Research

The Office of Management and Budget (OMB) defines minimum standards for maintaining, collecting and presenting data on race and ethnicity for all federal reporting agencies (including HRSA) in OMB Directive 15: http://www.whitehouse.gov/omb/fedreg_1997standards.

The standards were revised in 1997 and include two ethnic categories (Hispanic or Latino and Not Hispanic or Latino) and five racial categories (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White). The categories in this classification are social-political constructs and should

not be interpreted as being anthropological in nature. HRSA is required to use these definitions to allow comparisons to other federal databases, especially the census and national health databases. Federal agencies will not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

Collection of this information and use of these categories is required for research that meets the definition of clinical research. The collection of greater detail is encouraged, for example on racial or ethnic subpopulations. However, any collection that uses more detail must be designed in a way that data can be aggregated into these minimally required OMB categories. Use self-report or self-identification to collect this information from subjects by asking two separate questions – one on ethnicity and one on race. Collect ethnicity information first, followed by the question on race and provide participants with the option to select more than one racial category. Participants also have the option not to identify. When feasible, HRSA encourages investigators to include information about individuals who select more than one racial category and consider that data in their analyses. Participants who self-identify with more than one racial category should be reported under the "More than one race" category of the report. The following definitions apply to the minimum standards for the ethnic and racial categories.

Ethnic Categories:

- **Hispanic or Latino:** A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino."
- **Not Hispanic or Latino**

Racial Categories:

- **American Indian or Alaska Native:** A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.
- **Asian:** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)
- **Black or African American:** A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."
- **Native Hawaiian or Other Pacific Islander:** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
- **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Ethnic/Racial Subpopulations: In addition to OMB ethnic and racial categories, each ethnic/racial group contains subpopulations that are delimited by geographic origins, national origins, and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of specific origins and/or cultural heritage. Attention to subpopulations also applies to individuals who self-identify with more than one race. These ethnic/racial combinations may have biomedical, behavioral, and/or socio-cultural implications related to the scientific question under study.

5.8 PHS Policy on Inclusion of Children

PHS policy requires that children (i.e., individuals under the age of 18) must be included in all clinical research conducted or supported by HRSA unless there are clear and compelling reasons not to include them. Therefore, applications proposing clinical research must include a description of plans for including children. If children (or a subset of children) will be excluded from the research, the application must include an acceptable justification for the exclusion. For additional details and guidance, please refer to Section 4.3 of these instructions.

The involvement of children as subjects in research must be in compliance with all applicable subparts of 45 CFR part 46 as well as with other pertinent federal laws and regulations.

IRBs have special review requirements to protect the well-being of children who participate in research. These requirements relate to risk, benefit, parental/guardian consent, and assent by children, and to research involving children who are wards of the state or of another institution. The local IRB approves research that satisfies the conditions set forth in the regulations.

5.9 Research on Transplantation of Human Fetal Tissue

In signing the application Face Page or checking the “I agree” box on line 17 of the SF-424 R&R Cover Form, the Authorized Organization Representative of the applicant organization certifies that if research on the transplantation of human fetal tissue is conducted, the applicant organization will make available, for audit by the Secretary, HHS, the physician statements and informed consents required by section 498A (b)(2) and (c) of the Public Health Service Act, 42 U.S.C. 289g (b)(2) and (c), or ensure HHS access to those records, if maintained by an entity other than the applicant organization.

5.10 Research Using Human Embryonic Stem Cells

In signing the application Face Page or checking the “I agree” box on line 17 of the SF-424 R&R Cover Form, the Authorized Organization Representative of the applicant

organization certifies that if research using human embryonic stem cells is proposed, the applicant organization will identify human embryonic stem cells (hESCs) to be used from the NIH Registry (http://stemcells.nih.gov/research/registry/), or, if a specific cell line cannot be referenced at the time of application, certify that one from the NIH Registry will be used, in accord with the NIH Guidelines on Human Stem Cell Research (http://stemcells.nih.gov/policy/2009guidelines.aspx). The Authorized Organization Representative further certifies that the hESCs will be used in accordance with any restrictions associated with the line as cited on the Registry (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-029.html). See http://stemcells.nih.gov/info/Pages/default.aspx for additional information on stem cells, federal policy statements, and guidelines on federally funded stem cell research.

5.11 ClinicalTrials.gov Requirements

In signing the application Face Page or checking the "I agree" box on line 17 of the SF-424 R&R Cover Form, the Authorized Organization Representative of the applicant organization certifies that if the research is an applicable clinical trial under Public Law 110-85, the applicant organization will be in compliance with the registration and reporting requirements of Public Law 110-85 (Section 4.1.6).